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Food Drug Cosmetic Law Journal

APRIL • 1951

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R. E. CURRAN, K. C.

Chemical Additives . . . . . .
J. L. ST. JOHN

The Food Law Is Reasonable . . . . . .
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Keeping Food Clean . . . . . .
H. G. UNDERWOOD

Procedure in California . . . . . .
BAYARD RHONE

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The monthly FOOD DRUG COSMETIC LAW JOURNAL succeeds the FOOD DRUG COSMETIC LAW QUARTERLY and continues its editorial policy. That policy is to record the progress of this law and to provide a constructive discussion of it, according to the highest professional standards. The QUARTERLY, established in March, 1946, was the original publication on this law. The JOURNAL, instituted in March, 1950, is the only forum for current discussion of this law and it renders an important public service. For it is an invaluable means (1) to create a better knowledge and understanding of this law, (2) to promote its due operation and development, and (3) thus to effectuate its great remedial purposes. In short: while this law receives normal legal, administrative, and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; and the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Giving an international note to this month's JOURNAL is **R. E. Curran's** outline of the historical development of food and drug laws in the United Kingdom. Mr. Curran is the author of two other articles printed recently in this magazine—last month's "Standards in Canada," a paper which he presented at the Sixth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, and a comparison of Canadian and United States food and drug laws, included in last October's JOURNAL.

Mr. Curran is legal adviser to the Canadian Department of National Health and Welfare. He was appointed a Kings Counsellor by the government of Canada in July, 1950.

J. L. St. John, author of the article on chemical additives in foods, has authored or coauthored over 200 scientific papers on phases of agricultural biochemistry and analytical chemistry. Present Executive Secretary of the Food Protection Committee of the National Research Council, Mr. St. John has engaged in research in agricultural biochemistry and related fields for many years. He has been on the faculties of the University of Illinois and Purdue University, and is now serving as Chairman of the Department of Agricultural Chemistry and State Chemist at the State College of Washington.

An earlier Chairman of the Chemistry Division of the Pacific A. A. A. S., Mr. St. John has organized national lecture tours of well-known chemists for the American Chemical Society, participated in the organization and served as first president of the Association of Economic Poisons Control Officials. Organizer of the ACS's Symposia on Pesticides for the San Francisco and Atlantic City meetings, he has also participated in the organization of the recently formed Pesticide Subdivision of that society and is now serving as its chairman.

Specific problems that have come up under the jurisdiction of the federal Act are discussed by **L. M. Beacham,** Chief of the Canned Food Branch of the FDA. Well known to readers of the JOURNAL, Mr. Beacham has written on such subjects as "Why and How—Standard Making" and "Organoleptic Examination of Processed Foods" in past issues.

Since he first joined the Administration in 1934, Mr. Beacham has kept abreast of improvements and technical changes in processing methods. From visits and inspections of canneries and freezing plants throughout the country he has developed an extensive knowledge of standards of identity, quality and fill of container.

He was graduated from the University of South Carolina and did his graduate work at Rutgers University. Appointed to his first position with the Administration, that of inspector of canned shrimp in the Supervisory In-

spection Service, in 1934, Mr. Beacham later became a chemist in the Canned Food Branch of the Food Division and was subsequently appointed Assistant to the Chief of the Division in 1941 and Chief in 1949.

Fifteen years of experience with the Beech-Nut Packing Company give **R. K. Phelan** the background for his discussion of the problems involved in the manufacturing of baby foods. Serving first in the food laboratory there, Mr. Phelan then spent eight years in chewing gum manufacturing; which latter included three years in the East Indies as Far Eastern manager for the purchase and processing of chicle-type gums.

He returned to technical work as Assistant Research Director in 1945. In this capacity he is concerned with both control and research on all products manufactured by Beech-Nut. Training for this work was received from Dr. S. C. Prescott under whom he studied at the Massachusetts Institute of Technology.

Practical applications of Section 402 (a) (3) and Section 402 (a) (4) definitions of adulteration are explained in this issue by **H. G. Underwood,** a Food and Drug Officer. Dr. Underwood did his undergraduate work at the College of Emporia in Kansas and received both his master's and doctor's degrees in organic chemistry from the state university in Lawrence.

After a year as an associate professor of chemistry at Bethany College in Lingsborg, Kansas, Dr. Underwood entered the federal service as chemist in 1935 at the Chicago station. He has since then served as a chemist at Cincinnati, as Chief Chemist at New Orleans and as Assistant Chief of the Central District, before joining the Administration's Division of Program Research.

Bayard Rhone, Deputy Attorney General of California, deals with his state's Pure Food and Pure Drugs Acts from the procedural standpoint. His article was originally a paper which he presented before the Panel on Food, Drug and Cosmetic Law at the California State Bar Convention last year. A graduate of the University of Southern California where he received both his A. B. and LL.B., Mr. Rhone has held his present office since 1933. Since 1935 he has been the advisor in Southern California to the State Department of Public Health, including the Bureau of Food and Drug Inspections.

His legal work for the bureau concerns the constitutionality of various phases of the two state acts, injunctions to restrain the sale or distribution of food or drugs deemed to be in violation of the various statutes and the condemnation or forfeiture of the offending foods and drugs. A major case handled by Mr. Rhone in recent years was one resulting in the compelling of the City of Los Angeles and eleven adjacent cities to build adequate sanitation facilities—culminating in the construction of the $42,000,000 Hyperion Sewage Treatment Plant.

In Congress

Switch of Food and Drug Jurisdiction.—Both houses heard bills introduced which recommended the submitting to Congress of a plan for placing regulatory functions respecting food products under the Department of Agriculture and those respecting drugs under the Public Health Service. Formulators of the plan would be the Secretary of Agriculture, the Federal Security Administrator and the Federal Trade Commission. The bills—H. R. 3308 and S. 1149—provide for the reorganization of the Department of Agriculture in accordance with recommendations of the Commission on Organization of the

Executive Branch of the Government. They are intended primarily to promote economy and reduce expenditures by eliminating duplicating and overlapping offices and facilities and by utilizing fully all the services of the Department. S. 1149 has been sent to the Senate Committee on Expenditures in the Executive Department for study, while H. R. 3308 is under consideration of the House Committee on Agriculture.

National Chemistry Week.—In recognition of the diamond jubilee celebration of the American Chemical Society, a joint resolution (S. J. Res. 55) was introduced in the Senate authorizing the President to proclaim the week September 2-8, inclusive, as National Chemistry Week. Introduced on March 20, the bill was referred to the Committee on the Judiciary.

Proposed Changes.—Four amendments to the Federal Food, Drug, and Cosmetic Act (H. R.'s 3254, 3255, 3256, 3257) were introduced in the Senate on March 15 by Representative Miller of Nebraska. The first (H. R. 3254), would amend Section 602 of the Act to require that soaps and detergents bear labels stating their "common or usual name[s]" and, if fabricated from two or more ingredients, the names of such and the percentages contained therein. H. R. 3255 would enlarge the definition of cosmetic in the Act to include soap, and H. R. 3256 would require the labeling of bread and rolls, stating the percentage of shortening, solids of milk or milk products and solids of egg or egg products they contain.

A new paragraph is recommended (H. R. 3257) to amend Section 201 of the Act to read:

"(q) The term 'chemical additive' means any substance (including products resulting from changes in such substance after use) intended to be used—

"(1) to preserve or alter any food or any characteristic thereof, or

"(2) in substitution, wholly or partly, for any food or any ingredient thereof, or

"(3) as a pesticide or for other purpose in producing, processing, packing, or holding food if such use is likely to result in contamination of such food, . . ." if such substance is not generally recognized as nonpoisonous and nondeleterious by experts. Or, if poisonous or deleterious, the substance is required in the production of food, it shall be considered a chemical additive if it is not recognized by experts as safe for use. An entire section on chemical additives would be added to the Act's chapter on food by this bill. All four bills have been referred to the Committee on Interstate and Foreign Commerce.

Control of Poisonous Weeds.—To protect the livestock industry from losses caused by poisonous weeds, a bill was introduced in the Senate March 5 which would provide for their eradication and control. If passed, the bill would also provide for the maintenance and development of valuable forage plants on range and pasture lands. It would empower the federal government either independently or in cooperation with the states, private associations or individuals, to "control, suppress, and eradicate" such harmful weeds—particularly the halogeton glomeratus. The Secretary of Agriculture would be authorized by the bill to allocate sums required to whatever agency has jurisdiction over ranges or pasture land where poisonous weeds are discovered; to determine necessary measures to combat them, and to direct and carry them out. The bill is now being studied by the Committee on Interior and Insular Affairs. (S. 1041.)

"Butter" than Nothing.—Now with the Committee on Armed Services is a bill introduced in the House March 13 which would provide for the serving of oleomargarine or margarine to Navy men. The bill, H. R. 3207, provides for the insertion in the Navy ration statute of the words "oleomargarine" or "margarine" after the word "butter."

In the State Legislatures

New Hampshire Prohibitions. — The New Hampshire Food and Drug Law has been amended to enumerate several prohibited acts, among which are the sale or delivery, holding or offering for sale of any food or drug that is adulterated or misbranded; the adulteration or misbranding of any food or drug; the receipt or delivery of such food and drugs; the dissemination of any false advertisement; refusal to permit entry or inspection; giving of a guaranty under certain circumstances; and the removal or disposal of a detained or embargoed article in violation of Section 20, which deals with the authority to embargo and condemn. Sections 6 and 8 of the New Hampshire law, relating to misbranding, are repealed, and a new section relating to authority to embargo and condemn is added [CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 53,301].

Restriction on Hadacol Advertising. —Passed by the Illinois House March 28 was a bill (H. 45) urging the House to request Senator Leblanc, discoverer of Hadacol, to refrain from using testimonials of young children in advertising a product which contains from twelve to fourteen per cent alcohol, and to stop further publication of such advertisements in Illinois.

Barbituric Acid.—Awaiting action of the Arkansas Senate is H. 195, passed February 23 by the House, which would prohibit the sale of barbituric acid and compounds except to wholesale drug houses, chemists' dispensing pharmacies and licensed physicians.

New Mexico Drug and Cosmetic Act. —Enacted by the New Mexico legislature is a law whose essential provisions with respect to food control are similar to the Federal Food, Drug, and Cosmetic Act. The new legislation governs the manufacture, processing, packing, storing and advertising of foods; defines terms and enumerates prohibited acts; provides for injunction proceedings, penalties and guaranty, seizure, emergency permit control, regulations, inspections, publicity and definitions and standards of identity; defines adulteration and misbranding; provides control of minor violations, tolerances and false advertising; and declares violations to be misdemeanors (H. 80).

In the Food and Drug Administration

Antibiotic Amendments.—Regulations governing the certification of batches of antibiotic and antibiotic-containing drugs have been amended as follows: provisions have been made for the use of a preservative in the dry mix of procaine penicillin for aqueous injection, for modifying the packaging requirements of an aqueous suspension of procaine penicillin, for the optional use of a preservative as an ingredient in streptomycin ointment and for a change in the expiration date of certification of this drug from twelve months to twenty-four months after the month during which it was certified, for the optional use of two or more suitable sulfonamides in the manufacture of streptomycin tablets and dihydrostreptomycin tablets intended solely for veterinary use, and for the optional use of a suitable and harmless local anesthetic in the manufacture of

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British Food and Drug Law —A History

By R. E. CURRAN, K. C.

The Author Traces the Development of Food Law in the United Kingdom as the Foundation of "a Body of Law to Which the English-Speaking World Owes So Much"

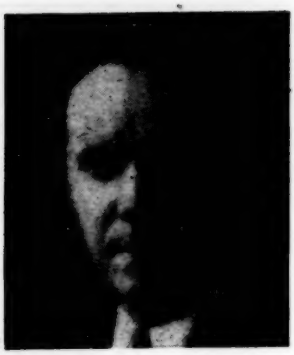
THE SOCIAL IMPORTANCE of the food and drug laws has been the subject of frequent utterance and, indeed, has provided a basic theme running through a great deal of what has been written on their philosophy.

While many food laws, and to a lesser extent, drug laws, have their roots in antiquity, food and drug laws dealing with their subject in a generic rather than in an individual way, are of comparatively modern development.

The pattern of the laws in the English-speaking countries has, to a very great extent, many points of resemblance and, in some cases, of similarity.

A historical examination of many of these laws strongly suggests that any aspects of resemblance or similarity are not entirely coincidental, but are traceable to the early food and drug laws of England. Although the laws of other countries may have developed

Mr. Curran Is Legal Adviser, Department of National Health and Welfare, Canada



along divergent lines with some new concepts, the importance of the English laws cannot be overlooked.

While the expression, food and drug laws, is extremely broad and would include a variety of statutes relating to some aspect or other of the production, manufacture, distribution, or sale of foods and drugs, the layman's conception of this would be contained in that law which protects him from injury and fraud. The scope of this article will, therefore, be confined to the law contained in the food and drug statutes, and will not take in the variety of related or incidental laws which may offer a form of protection, but which have for a primary purpose, something else.

Those who attended the Washington meeting of the Division on Food, Drug and Cosmetic Law, in the Section of Corporation, Banking and Business Law of the American Bar Association, had the pleasure of hearing Mr. Charles A. Adams, Director, Food Standards and Labeling Division of the British Ministry of Food, explain certain aspects of the English food law.[1]

Mr. Adams dealt substantially with the present law including many of the wartime changes and the endeavors of the administration in the matter of food standards and labeling to bring the situation more in conformity with developments in the United States and Canada. It may, however, be of some interest to examine briefly,

[1] 5 FOOD DRUG COSMETIC LAW JOURNAL 642 (1950).

the historical development of the food and drug laws of the United Kingdom of Great Britain and Northern Ireland. This comprises England, Scotland, Northern Ireland, Wales, The Isle of Man, and the Channel Islands.

Historically, the origin of the present laws is clear and easy to trace. A consideration, however, of the laws applicable in the respective areas of the United Kingdom, on a general basis of comparison, is one of some complication and difficulty, and requires a preliminary examination of the constitutional positions occupied by the various areas which comprise the United Kingdom.

Legislative Situation in United Kingdom

The United Kingdom as a unitary state has no jurisdictional problems as to the authority of its Parliament to enact laws for all portions of it.

This general statement is, however, subject to a number of qualifying conditions. Despite, therefore, a central government which would suggest uniform laws, there are special laws in force in Scotland respecting food and drugs which are different to the laws in force in England, and which, in turn, are different to the laws in force in Northern Ireland. If this were not sufficiently complicated in itself, the situation is further complicated by the fact that certain portions of the laws in force in England are expressly made applicable to Northern Ireland and to Scotland with additional provisions in the case of Scotland declared to be in force subject to the substitution of particular words and phrases where necessary or applicable.

Among the qualifying conditions respecting the central form of government is that arising from the Government of Ireland Act of 1920, which conferred a constitutional status on Northern Ireland, with power in its own parliament to make laws for its peace, order, and good government, in addition to a number of specific matters. The subject of food and drugs, therefore, is regarded within the competence of the Parliament of Northern Ireland subject, however, to the overriding authority of the Parliament of Great Britain.

While Scotland does not have any parliament of its own or general legislative authority per se, regard is, however, invariably

given by Parliament to differences in Scotland as to legal procedures and customs and tradition.

It is usually the case, therefore, that laws of the United Kingdom Parliament which may have local application will expressly state the extent of their applicability, if any, to Scotland and to Northern Ireland.

While this thumbnail outline of the legislative situation in the United Kingdom respecting the food and drug laws is very much of an oversimplification, it is, perhaps, sufficient to emphasize the individual and special attention which must be paid to each of the areas mentioned, and in outlining in chronological sequence the development of the food and drug laws, these particular aspects will be further mentioned.

Ancient Food Law

The ancient food law dealt with specific articles of food and was concerned, not so much with quality as we understand it, but with aspects of fraud, and frequently with a strong leaning towards economic considerations. A study of some of these early laws is of more than passing interest, because they provide a legal mirror in which are reflected many of the customs and conditions of bygone days. For example, while many of us regard price control as an invention of modern war, historically this is not so.

Apart from very ancient examples of price control in Greece and in Rome, we find interesting instances in the laws of England. As early as 1552, an ordinance of the Aldermen of the City of London had for the evil of profiteering, a realistic treatment which might well form a model for the modern proponents of controls as a solution of present soaring prices. That ordinance proclaimed that the butchers of London should sell beef, mutton, and veal of the best quality for one penny and a farthing a pound and, "Yff thay wyll nott thay to loysse ther fredom for ever and ever." [2]

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[2] *The Englishman's Food*, by Drummond & Wilbraham, p. 32.

Act of 1860

While the early statutes were concerned either with individual commodities or with particular aspects of a social need, it was not until 1860, that there appears to have been given to the subject of food in its generic sense, any legislative consideration. In that year there was enacted an act entitled: "An Act for preventing the Adulteration of Articles of Food or Drink," which went on to recite:

> WHEREAS the practice of adulterating Articles of Food and Drink for Sale, in fraud of Her Majesty's Subjects, and to the great Hurt of their Health, requires to be repressed by more effectual laws than those which are now in force for that Purpose.[3]

The substantive portion of this law was contained in Section 1 which provided in part as follows:

> (1) Every Person who shall sell any Article of Food or Drink with which to the Knowledge of such Person any Ingredient or Material injurious to the Health of Persons eating or drinking such Article, has been mixed, and every Person who shall sell as pure or unadulterated or not pure shall for every such Offence . . . .

Inadequate as this legislation proved to be to meet the evils of the day, modern legislation owes to it a great deal. Not only did it mark the first step towards a more comprehensive treatment of the law respecting the sale of impure foods, but it also introduced the official analyst who has proved such a steadfast and dependable companion through the succeeding evolutionary years.

Amendatory Act of 1872

This enactment had a limited value in that it dealt only with the actual sale of foods and not with their manufacture. This limitation was soon recognized, and, in 1872, it was sought to be overcome through an amending act entitled "An Act to amend the Law for the prevention of Adulteration of Food and Drink and of Drugs," which went on to recite:

> WHEREAS the practice of adulterating articles of food and drink and drugs for sale, in fraud of Her Majesty's subjects, and to the great hurt of their health and danger to their lives, requires to be repressed by more effectual laws than those which are now in force for that purpose.[4]

Its substantive provisions were contained in the first three sections which extended the 1860 act and were intended to cover all

[3] 23 and 24 Victoria, cap. 84.

[4] 35 and 36 Victoria, cap. 74.

possible and foreseeable offenses relating to the manufacture and sale of food, as well as of drugs.

These sections in brief penalized:

1. The willful admixture with an article of food or drink of any injurious or poisonous ingredient to adulterate it for sale, and the willful admixture with any drug of any ingredient to adulterate it for sale;

2. (i) The sale of an article of food or drink with which, to the knowledge of the vendor any ingredient injurious to the health of persons consuming it, had been mixed;

(ii) The sale as unadulterated of any article of food or drink or any drug which was adulterated;

3. The sale of an article of food or drink or any drug which the vendor knew to have been mixed with any other substance with intent fraudulently to increase its weight or bulk, and who did not declare such admixture to the purchaser before delivery of the article.

Apart from Section 3, which is worthy of special mention, the legislation is important for at least two reasons. In the first place, it gave drugs a legislative recognition equal to, or at least comparable with foods, and in the second place, it formed the pattern from which the first Canadian Food and Drug Law in 1874 was modeled.

Section 3, as a perusal will indicate, is worthy of particular consideration.

Here, indeed, is a bold if somewhat naive attempt to promote between a dishonest vendor and an unsuspecting purchaser, a slight measure of honesty and fair dealing. More important than this, however, it represented a small but determined toe in a door which subsequent legislation opened so wide in its requirements as to informative labeling.

The facts of many of the reported cases of the day are such as to make one wonder whether there existed such a person as an unsuspecting purchaser, or a completely honest vendor. The cases would, moreover, suggest that adulteration was so common as to impute to the purchaser a form of constructive knowledge that when he bought spices, it was altogether likely that they would be admixed with flour,

that cocoa would be admixed with starch, sugar with sand, tea with sweepings, and so on along the line of the favorite admixing materials of the day.

The courts, moreover, expressly held that it was not necessary to state the nature or quantities or the materials admixed, so long as the purchaser was alerted by the magic word "mixture."

For example, a grocer who mixed mustard with flour and tumeric successfully brought himself within the protective provisions of Section 3 by a notice stating, "warranted free from injurious admixture, but not sold as pure mustard." *Pope v. Tearle* (1874), L. R. 9 C. P. 499.

In looking at Section 3 for the first time, however, one would wonder whether it did not contain a clerical error or legislative omission, or if not, whether Parliament did not have its legislative tongue in its cheek in enacting such a provision. Whatever is the explanation, its dubious benefit or protection must soon have been recognized as inadequate for it was repealed in 1875 in the new Food and Drugs Act, which replaced the statutes of 1860 and 1872.

Food and Drugs Act of 1875

The section in the 1875 enactment which dealt with this aspect completely reversed the effect of Section 3 by limiting the protection of such a notice to cases where the admixture was noninjurious, was not intended fraudulently to increase bulk weight or measure or to conceal inferior quality. Such a reversal of intent must have come as a rude awakening or shock to vendors, who presumably had taken considerable comfort from the former legislative tolerance.

One may well imagine the feeling of injured innocence to find, for example, that under the 1875 legislation, coffee which consisted of only eighty-five per cent chicory and fifteen per cent of coffee, was no longer within the protection of the statute by a simple declaration that it was a "mixture." *Horder v. Meddings* (1880), 44 J. P. 234.

The question of notices may be left for the moment as it comes up again in considering the provisions of succeeding enactments.

The statute of 1872, notwithstanding its broader scope and more imaginative, if not more realistic attempt to deal with at least one aspect of an evil, enjoyed a short legislative life, for in 1875 it was

repealed by "An Act to repeal the Adulteration of Food Acts, and to make better provisions for the Sale of Food and Drugs in a pure state." This act went on to say:

> WHEREAS it is desirable that the Acts now in force relating to the adulteration of food should be repealed, and that the law regarding the sale of food and drugs in a pure and genuine condition should be amended.[8]

Notwithstanding the importance of the earlier enactments, the act of 1875 which is commonly referred to as The Sale of Food and Drugs Act 1875, is the ancestor from which substantially all food and drug laws are descended and from which they inherit whatever family resemblance they possess.

The importance of this legislation in its effect on the character, molding and development of later food and drug laws, warrants some brief explanation of its provisions.

Food was defined to include every article used for food or drink by man, other than drugs or water, and drugs to include medicine for internal and external use. The definition of a drug remains unchanged today, but in the case of food, the definition had undergone substantial amendment. The definition now contains any substance intended for use in the composition or preparation of food, any flavoring matter or condiment, and any coloring matter intended for use in food.

The substantive provisions of this statute are contained in its first nine sections, and indeed, these provisions remain either intact, or in a somewhat altered form in the present food and drug laws respectively applicable in the various parts of the United Kingdom, as well as in many other parts of the Commonwealth.

Substantive Provisions of 1875 Act

Sections 3 and 4 provided that no person should mix, color, stain, or powder any food or drug with any ingredient or material so as to render it injurious to health, or any drug with any ingredient or material so as to affect injuriously its quality or potency with intent that it be sold in that state. The sale of such article was, moreover, prohibited.

Section 5, however, provided a defense, where absence of knowledge that the article was adulterated was proved, and where the vendor

[8] 38 and 39 Victoria, cap. 63.

established that he could not, with reasonable diligence, have obtained that knowledge.

Section 6 prohibited the sale to the prejudice of a purchaser of any article of food or drug, not of the nature, substance, and quality demanded. The section, however, expressly provided certain defenses in recognition of conditions which would otherwise have made the section inoperative. It accordingly provided that there should be no offense where noninjurious matter was added to a food or drug, and was required for its production or preparation as an article of commerce in a fit state for carriage or consumption, and not fraudulently to increase bulk, weight or measure, or to conceal inferior quality. It also provided that it should be no offense under the section if the food or the drug was unavoidably mixed with some extraneous matter in the process of collection or preparation.

Section 7 prohibited the sale of any compound article of food or drug not composed of ingredients in accordance with the demand of the purchaser.

Section 8, which reversed the effect of Section 3 of the 1872 act, provided a defense with respect to the sale of an article which had been mixed with any matter or ingredient not injurious to health, and not intended fraudulently to increase its bulk, weight, or measure, or to conceal its inferior quality if, at the time of delivery, the vendor supplied to the purchaser a notice by a label distinctly and legibly printed on, or with the article or drug, to the effect that it was mixed.

Section 9 prohibited any person from abstracting from an article of food, any part of it so as to affect injuriously its quality, substance or nature, with intent that the article be sold in its altered state without notice, and prohibited the sale of such an article so altered, without disclosure of the alteration.

These provisions formed not only the backbone of the food and drug legislation which is still applicable, but also the framework on which so many of the food and drug laws of the Commonwealth were patterned.

Importance of Section 6, 1875 Act

Of all the sections which were provided in this enactment, Section 6 was easily the most important. It was then, and still continues

to be, the keystone of the enforcement sections. It is under Section 6 that the bulk of all of the English jurisprudence has been decided. This is possibly explainable, for a number of reasons.

In the first place, it is broad enough to found a charge which might also fall under one or other of the sections of the act. It, therefore, because of its convenience and the body of jurisprudence which it soon created, became the favorite section under which to lay charges.

A further reason for its choice lay in what is possibly the greatest defect of the legislation. Neither this legislation nor subsequent legislation, until 1938, recognized the necessity to prescribe legal standards of requirements for a food or drug. This lack of authority was possibly the greatest handicap under which the administration had to labor in enforcing the law.

Section 6 came closest of all the sections to overcome this difficulty, because a purchaser who did not receive an article of the kind generally supplied and ordinarily expected, might be said to be prejudiced, unless adequately warned.

The section, therefore, became a cornerstone around which there gradually emerged what might be regarded as judicial standards which, in the course of time, came to be accepted as the minimum requirements inherent in the composition of certain commodities.

The inference which seems to be inescapable from examining a number of these early decisions is that the doctrine of *caveat emptor* was not to be lightly or easily replaced by any paternalistic attitude towards a consumer, such as we take for granted today.

Apparently so long as the purchaser was put upon his enquiry by a notice to the effect that he was getting a mixture, the vendor had not only satisfied his conscience but also the requirements of the law. Even the courts did not appear to be overly severe in criticizing notices which ranged from ambiguity to outright deceit, and of which, some examples are later given in this article.

As might be expected, in developing a new philosophy with respect to such an important subject as the food and drug law, it soon ran up against the astute legal talents of the day, and many were the attempts made to drive the traditional coach and four through its provisions.

In the case of *Davidson v. M'Leod*, 42 J. P. 43, which was one of the earliest of these legal excursions, the Court of Justiciary in Scotland held that the sale of an adulterated article to a food and drug inspector for the purpose of analysis could not be to his prejudice as he was not using his own money in buying it, and that the expressions "nature, substance and quality," could not be disjoined, and that proof of all three were necessary in establishing the commission of an offense. This decision, however, was not followed in England in the case of *Hoyle v. Hitchman* (1879), 4, Q. B. D. 233.

Further defenses were raised with respect to the taking of samples, and whether a sample could be taken while an article was in process of delivery, or whether it could be taken only at the place of sale. Cases arose where vendors refused to sell to inspectors, and many other difficulties developed out of the administration of what was then regarded as the last word in a food and drug law.

Act of 1879

All of these defenses were given legislative recognition through the passing, in 1879, of "An Act to amend The Sale of Food and Drugs Act 1875." [6]

In addition to dealing with the matters which had proved bothersome, it dealt with what was then, and may still be, a very contentious matter: the proper strength of spirits.

Supervising honesty and fair dealing in the sale of spirits seems to have been considered one of the major responsibilities of the inspectoral staff. It was then by no means an uncommon practice for publicans to dilute their spirits to a more profitable strength. As there was no prescribed legal strength, the only means of reaching such publicans was through the prohibition of selling to the prejudice of the purchaser, an article not of the nature, substance or quality demanded.

The legislation recognized these difficulties by fixing a legal strength which would be considered satisfactory and below which the purchaser was deemed to be prejudiced.

As already explained, it was, however, a defense if an appropriate notice was given to the purchaser at the time of sale respecting the

[6] 42 and 43 Victoria, cap. 30.

alcoholic strength. Many were the forms of notice which were devised by cunning publicans to inform, but not to warn the purchaser.

The following is an example of one of such notices which was placed in a public house:

> All spirits sold in this establishment are of the same quality as heretofore, but to meet the requirements of the Food and Drug (Adulteration) Act, they are now sold as diluted spirits; no alcoholic strength guaranteed. *Gage v. Elsey* (1883) 10 Q. B. D. 518.

It was held that there was no sale to the prejudice of the purchaser, although later decisions dealing with a notice substantially to the same effect cast doubt on the authority of this decision.

This amendment seemed to settle the most vexing problems common to the manufacture and sale of food and drugs, and in succeeding enactments, the legislative emphasis was directed almost entirely to dairy products.

The impetus which the subject of drugs received, between 1872 when it was first added to the statutes, and 1879, seems to have been lost in later enactments. So strong, moreover, was the searchlight which the legislation turned on dairy products that even other foods were cast into shadow. Whether the emphasis was actually necessary to meet a current evil in terms of health, or an evil in terms of economic consideration for an industry, is difficult to determine. Whatever may have been the reason, all subsequent legislation up to the present has placed an emphasis on dairy products which, on a comparable basis in Canada, would seem completely disproportionate to the health aspects involved in the production and sale of these commodities.

Emphasis on Dairy Products

By way of example, in 1887, there was enacted the Margarine Act [7] which protected the manufacture and sale of butter. In 1899, the Sale of Food and Drugs Act 1875 [8] was again amended, firstly by incorporating therein the provisions of the Margarine Act, but also to make more specific provision respecting the sale of such dairy products as milk, cream, butter, and cheese. This enactment gave a limited recognition to a standard for milk and dairy products by authorizing the Board of Agriculture to make regulations for determining what

[7] 50 and 51 Victoria, cap. 29.

[8] Cap 62 and 63 Victoria, cap. 51.

deficiency in any of the normal constituents of genuine milk, cream, butter, or cheese, or what addition of extraneous matter or proportion of water therein, should raise a presumption that the article was not genuine, or was injurious to health.

As in the case of the sale of spirits already mentioned, many were the devices employed with respect to dairy products to inform, but not to warn the purchaser, and it may be of interest to mention one or two of the more amusing of these.

In the case of *Pearks Gunston and Tee, Ltd. v. Houghton* (1902) 1 K. B. 889, butter had been blended with milk in such a way as to contain some 7.8 per cent of moisture above the permissible maximum of sixteen per cent, and in the establishment which sold this product there was a notice to the following effect:

> Notice—Pearks butter as sold at this establishment is choicest butter blended with English full cream milk by new and improved machinery, whereby it retains about 20-25 per cent of moisture and acquires a delicacy of flavor which has made Pearks butter so famous.

In this case the court held that the vendor was protected by the notice and the sale was not to the prejudice of the purchaser.

In another case, milk was sold from a can which bore a label:

> Under the Food and Drugs Act, all milk sold from this can is more or less diluted, and is sold as such. No standard guaranteed.

Here again, it was held that no offense had been committed (*Dearden v. Whiteley* (1916) 85 L. J. K. B. 1420).

Reverting to legislation, in 1907, further provision was made for dairy products through the enactment of "An Act to make further provision with respect to the manufacture, importation and sale of butter and margarine and similar substances." [9]

This legislation provided that it should be construed as one with the Sale of Food and Drugs Act, although as the title would suggest, the entire subject matter was in relation to the products mentioned.

The Public Health Act of 1907

In the same year there was also enacted as a public health measure, the Public Health (Regulations as to Food) Act.[10] It is under the authority of this law that regulations were made respecting the use

[9] 7 Edward 7, cap. 21.

[10] 7 Edward 7, cap. 32.

of preservatives in food, and in fact, it was only under this legislation that any authority existed with respect to prescribing the addition or otherwise of such an ingredient to food.

Food and Drug Adulteration Act of 1928

In 1928, there was enacted the Food and Drug (Adulteration) Act of 1928.[11] This act was a consolidating statute to bring into one enactment, with some streamlining, all of the various food and drug enactments since and including the act of 1875. It did not represent any particular advance in the philosophy of the law, nor did it contain any substantially new or evolutionary concepts of the law respecting food and drugs. It has an importance, for a reason which is afterwards mentioned, in that it is the law still in force in Scotland.

Food and Drugs Act of 1938

In 1938, however, there was enacted the Food and Drugs Act of 1938,[12] which replaced the Food and Drug (Adulteration) Act of 1928. This enactment, although to some extent a consolidating enactment, was much more than that, for it recognized for the first time the necessity of authority to establish standards for foods, and to deal with advertisements and labels. The substantive provisions of this enactment remained substantially as in the original act of 1875, with the addition of provisions which recognized the growing force of labels and advertisements as a means of informing the customer.

Although Mr. Adams has dealt comprehensively with the effect of these changes, it may be convenient for the purpose of the continuity of this article, to make somewhat brief mention of them again.

The act of 1875 as shown in the summary given of its substantive provisions, contained exempting provisions where a substance was necessarily added to a food or drug, or where a constituent was abstracted, and the purchaser was informed.

The 1938 enactment carried this exempting provision somewhat further by limiting the effect to which a label could afford a defense, even under the circumstances as had been broadly dealt with in the act of 1875.

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[11] 18 and 19 Geo. 5, cap. 31.

[12] 1 and 2 Geo. 6, cap. 56.

The 1938 enactment, accordingly provided that the label should state explicitly the substance added or the constituent abstracted, and must be of adequate size, with the required information distinctly and legibly printed and conspicuously visible.

As a curious example of recognition of custom or usage, the statute goes on to provide that as respects a mixture, these requirements shall be deemed to be satisfied by a label which has continuously been in use without material variation since 1893, and bears a statement to the effect that the article is mixed, or by a label continuously in use, without any material variation since 1932, and "bears such a statement distinctly and legibly printed and unobscured by other matter on the label."

The legislation prohibited the furnishing with any food or drug of a label falsely describing the article or otherwise calculated to mislead as to its nature, substance, or quality, or the publication of an advertisement falsely describing any food or drug or otherwise calculated to mislead as to its nature, substance, or quality. Here again, exempting provisions were made for proof of absence of knowledge and means of knowledge of the false or misleading character of the label or the advertisement.

In addition to the rather substantial advance which the legislation made in the field of misbranding through more adequate control of labels and advertisements, the legislation contained provision for the first time to authorize the Minister of Health to make regulations prohibiting or restricting the addition of any substance to, and regulating generally the composition of food. To say that this constituted one of the most, if not the most revolutionary changes in the law is not an overstatement. It, for the first time, recognized the handicap under which both administration and enforcement had suffered in trying to achieve uniformity in matters pertaining to foods. As Mr. Adams pointed out, the war come along before this legislation became effective, and the development of its purpose was therefore not only delayed, but further affected by extraordinary conditions resulting from the war.

The 1938 legislation is, from the Canadian point of view, a curious combination of public health, licensing, and special, as well as general enactments, as its title would suggest, and which reads: "An Act to consolidate with amendments certain enactments relating to food, drugs, markets, slaughter houses and knackers' yard."

Part I of the legislation contains the substantive provisions of the act and also deals with unsound food, including its sale, examination, and destruction; precautions against contamination in the handling or storage of food, sanitary conditions in premises including registration and licensing, open air markets for foods in general, as well as special foods, such as ice cream, the procedure from a public health point of view in cases of food poisoning, and the sale of meat from knackers' yards.

Part II contains provisions with respect to milk, dairies, and artificial cream.

Part III contains provisions with respect to bread and flour, margarine, margarine cheese, butter, and milk-blended butter, ice cream, horseflesh, and shellfish.

Part IV contains provisions respecting the importation of foods into the United Kingdom.

Part V contains provisions with respect to markets, slaughterhouses, and cold-air stores.

Part VI contains the general and miscellaneous administrative provisions including those pertaining to legal proceedings.

Recent Legislation

To complete briefly the chronological developments of the food and drug laws, there was enacted in 1944, the Food and Drugs (Milk and Dairies) Act 1944;[13] in 1949, the Milk (Special Designations) Act 1949;[14] and in 1950, the Food and Drugs (Milk, Dairies and Artificial Cream) Act of 1950.[15] This latter enactment is peculiarly a consolidating enactment for it takes out of the Food and Drugs Act 1938, the whole of Part II which dealt with milk, dairies, and artificial cream, and repealed portions of the Food and Drugs (Milk and Dairies) Act 1944, as well as the whole of the Milk (Special Designations) Act 1949.

It is unnecessary to make mention here of the wartime legislation, as this has also been comprehensively covered by Mr. Adams.

Food and Drug Law in Northern Ireland

It may be convenient, however, to disgress at this point to deal with the situation in Northern Ireland, as well as in Scotland, from the point of view of food and drug laws.

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[13] 7 and 8 Geo. 6, cap. 29.
[14] 12 and 13 Geo. 6, cap. 34.
[15] 14 Geo. 6, cap. 35.

As already stated, the Government of Ireland Act of 1920 divided Ireland into Northern and Southern Ireland. It provided a parliament for each with a constitution not dissimilar in some respects to that contained in the Canadian Constitution under the British North America Act.

As different considerations now govern Southern Ireland, which is a republic and no longer a member of the Commonwealth, the references to Ireland will be confined to Northern Ireland. The Parliament of Northern Ireland under the act mentioned, was given power to make its own laws except as to certain matters which were reserved from it. There was, however, a proviso that laws of the Imperial Parliament would override any local laws, even though made with respect to matters within its assigned competence.

Section 61 of the act provided for the continuity of the laws then in force until otherwise dealt with by the Parliament of Northern Ireland.

At that time there was in force for the food and drug laws, the Sale of Food and Drugs Act 1875 as amended. This legislation accordingly continued in force, and as it has not been repealed by the Parliament of Northern Ireland, it remains in force at the present time.

For the sake of clarity, however, it perhaps should be mentioned that the Parliament of Northern Ireland has enacted some supplementary legislation relating to food and drugs. Here again, the legislation deals entirely with dairy products as, for example, the Milk Production Acts (Northern Ireland) 1934-1944, the Sale of Ice-Cream Act (Northern Ireland) 1937-1950, and the Margarine Act (Northern Ireland) 1939.

In addition to this legislation, Part IV of the English Act of 1938 dealing with importation of food into the United Kingdom, is specifically declared to be applicable to Northern Ireland.

There is some indication that the situation in Northern Ireland will, within the foreseeable future, be clarified and simplified in the form of consolidating legislation, but at the present time, the legislative picture is substantially as above outlined.

Food and Drug Law in Scotland

In Scotland, however, a still different situation exists, and to a casual observer, one which is equally complicated.

Although there is but one parliament for the United Kingdom with the exception mentioned in the case of Northern Ireland, full

regard has been given to Scottish customs, rights, privileges, and legal procedures by the Parliament of the United Kingdom.

In 1928, the consolidation of the then numerous enactments in the Food and Drugs (Adulteration) Act 1928 was made applicable to Scotland, with certain modifications and adaptations necessary to conform to Scottish laws and procedures. When this enactment was replaced by the Food and Drugs Act 1938, it was not, however, repealed insofar as Scotland was concerned, and the act of 1938 with certain exceptions, does not have application to Scotland. The law in that country is, therefore, contained in the 1928 act.

Among the exceptions mentioned, the portions of the 1938 act contained in Part IV relating to the importation of foods, are made applicable to Scotland. It is only with respect to this part of the act that the law in whole of the United Kingdom is uniform.

The portion authorizing regulations for the composition of foods is also made applicable to Scotland, as well as a number of less important provisions.

As in the case of Northern Ireland, there is also in force in Scotland special legislation affecting dairy products, but with the exception that it is legislation of the Imperial Parliament passed for Scotland only.

This, in brief, concludes a historical sketch of the development of the food and drug laws in the United Kingdom, and, in conclusion, one or two observations may be made with respect to this law in comparison with comparable treatment in other countries.

The first of these observations must, of course, relate to the question of food standards.

Food Standards

Mr. Adams has dealt with the efforts that are being made at the present time to deal with a problem that other countries faced many years ago. It may well be that the United Kingdom, through a later start in the matter of food standards, will be able to avoid the mistakes and difficulties which other countries have encountered, and so profit by their experience.

Similar considerations doubtless may also apply to the question of labels and advertisements. For a very long time the traditional honesty

of British merchants was in itself, accepted as a sufficient warranty to the consumer. Here again, however, considerable progress is being made in bringing labels into lines of uniformity with the standards and requirements of other countries.

In some cases, this could be accomplished only at the expense of tradition as, for example, the controversy respecting the use of the word "milk" in a famous brand of sherry which has been honored for some 150 years.[16]

Treatment of Drugs

A further aspect which is perhaps worthy of observation relates to the treatment of drugs. The present act and the preceding acts all purported to be drug acts as well as food acts, as their titles would suggest. Apart from the original act of 1875, which dealt with the subject of food and drugs in terms of some equality, later legislation practically ignored the subject of drugs although still purporting to deal with it.

The present act, which is described as a Food and Drugs Act is, however, essentially a public health and food statute. It is not, in any sense, as it would be understood either in the United States or Canada, a drug statute. Any examination of the English law with respect to the legislative treatment of drugs in comparison with the importance which the treatment of drugs receives in the United States and Canada, through the respective food and drug acts of those countries, is difficult to make, as it involves a consideration of other enactments as for example, The Medicines and Pharmacy Act 1941 and the Therapeutic Substances Act, to mention only two.

Out of some 103 sections of the 1938 act, a bare half dozen include the word "drugs" with the emphasis of all of the sections on the subject of food, and the public health aspect involved in its sale.

It is, moreover, a somewhat curious situation that none of the English statutes which deal with drugs, purport to establish any official standard for drugs, nor does the 1938 act give to the Minister of Health, power to establish standards for drugs as it does in the case of foods.

The *British Pharmacopoeia* which is a statutory publication, which is given the status of an official standard for drugs in Canada under

[16] *The Solicitor's Journal*, 7 Jan. 1950.

the Canadian law, is not accorded any such status or recognition in the United Kingdom.

True, some of the decisions have indicated that it is to be regarded as a very high authority, but with respect, it is submitted that this falls far short of according it official status.

Without developing this aspect further, one cannot be but somewhat confused or puzzled by the fact that not only is it difficult to ascertain the comparable laws in the United Kingdom relating to drugs, but that the treatment of the subject seems to be one of imbalance in contrast to the treatment of the subject in North America.

This observation is not made in any critical sense, and it is recognized that a visual comparison of textual provisions of a law is usually a most uncertain and inaccurate guide.

It is only with a true knowledge of the administration of the respective enactments, as well as the provisions, that any basis of comparison could fairly be made, and the article, therefore, does not attempt to make any such comparison, but merely to point out what must likely occur to any student in another country reading the English laws.

British Code of Standards

Before leaving the subject of drugs, however, the highly effective and realistic treatment which advertising receives under the "British Code of Standards in Relation to the Advertising of Medicines and Treatments," must be particularly mentioned.

Claims for drugs and treatments in relation to general as well as special conditions form a substantial bulk of the advertising material with which any food and drug law must be concerned.

While the majority of manufacturers and advertisers observe all of the canons of good taste, honesty, and integrity in portraying their products, this is unfortunately not of such general observance as to make special provisions in the law unnecessary.

Accordingly, the administration is constantly on the alert for the "hit and run" type of medicine advertiser, as well as the iconoclast in this field.

The democratic and practical way in which this administrative headache has been cured in Great Britain is worthy, not only of special

discussion, but some detailed description, for it presents an example or method in which other countries might well be interested.

This code has the approval of a number of organizations which are considered to be representative of the advertising industry and include The Newspaper Proprietors Association, The Newspaper Society, The Periodical Proprietors Association, The Proprietary Association of Great Britain, The Advertising Association, The Incorporated Society of British Advertisers, and The Institute of Incorporated Practitioners in Advertising.

The code sets out a number of general principles which should be regarded as minimum standards, to be observed by the parties concerned in advertising medicines and treatments.

Advertisements which do not conform to the standards as established by the code are not acceptable for publication. It will be appreciated that the code does not have any legal force, but as the organizations which endorse the principles constitute the bulk of the advertising industry of Great Britain, acceptance of these principles has become general.

The code is divided into three sections: Section 1 sets forth the general principles, Section 2 deals with restrictions imposed by statutes, and Section 3 provides examples of diseases, illnesses, or conditions for which medicines, treatments, products, or appliances may not be advertised.

Under the heading of "General Principles," advertisements are not accepted for, or which deal with, the following, among other matters, cures, illnesses requiring medical attention, and which are covered more specifically in Section 2 and 3; misleading or exaggerated claims as to the composition, character or action of the medicine or treatment, appeals to fears, diagnosis or treatment by correspondence, money-back offers, references to doctors or hospitals unless substantiated, illustrations intended or likely to convey a misleading impression, exaggerations, such as "magic, magical, miracle, miraculous," and testimonials which contain statements not otherwise permissible in the text of an advertisement.

Under Section 2 are listed a number of statutes which in turn impose restrictions. For example, the Cancer Act 1939, makes it an offense to advertise a treatment for cancer. Section 8 of the Pharmacy

and Medicine Act 1941, which is reproduced as part of the basic law, deals with matters for which advertisements may not be published. These constitute the principal statutes which are specifically dealt with in the code.

Section 3 sets forth a large number of illnesses or conditions of which the following are selected at random: obesity and slimming, indigestion, where the reference is to chronic or persistent, insomnia, where the reference is to chronic or persistent, sleeplessness, where the reference is to chronic or persistent, baldness, itch, pyorrhoea, skin diseases, where the reference is to "all" or "most" skin diseases or skin ailments in general.

In addition to these specific examples, there are many others relating to particular ailments or conditions, such as arthritis, anaemia, blood disease, blood pressure, phlebitis, thrombosis, ulcers, and varicose veins.

The code is specifically limited to advertisements to the public, and is not intended to restrict in any way, advertisements in technical journals or publications.

Insofar as Canada is concerned, a somewhat similar project has been under active consideration for the past five years. It is hoped that in the very near future a Canadian code concerned not only with drug claims, but also with food claims, may be brought out as a practical working agreement, which will have the support and approval of the industries concerned.

The above concludes the discussion on drugs, and there remains only cosmetics to be dealt with.

Cosmetics

The subject of cosmetics is not dealt with in any of the food and drug statutes. There is, accordingly, no legislation which is primarily concerned with cosmetics, and which would be comparable to the treatment of cosmetics in the Food, Drug, and Cosmetic Act of the United States or Canada.

It is hoped that this outline, without oversimplification or complication, has set forth broadly the historical development of the food and drug laws of the United Kingdom, and that it has done some justice to a body of law, to which all countries of the English-speaking world owe so much. **[The End]**

Safety of the Consumer Comes First When Using:

Chemical Additives

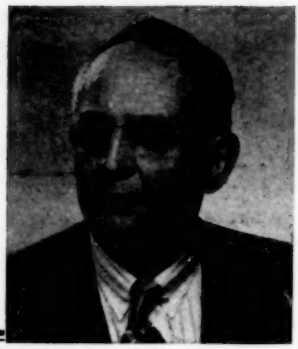
By J. L. St. JOHN

Since Chemicals *Do* Improve Nutritive Value and Texture of Foods, All Groups Concerned Must Cooperate in Seeing to Their Safe Use

"CAN IT BE SAFELY USED?" is one of the first questions asked about a chemical proposed for addition to food. Much has already been done to insure that the public is protected in cases where chemicals have been added to foods. Added consideration should be given to the problem to insure that each one of the chemicals added to food, either incidentally or intentionally, is not harmful, and that it will not be harmful even if there is continued use over long periods of time. To insure that such foods are safe for consumption requires the close cooperation of all groups concerned. These groups include the chemical manufacturer, the farmer who produces the food, the food processor, research and law enforcement agencies—both state and federal—the medical profession and other agencies such as the recently established Food Protection Committee of the National Research Council.

The production, processing, preservation and distribution of food is one of the more important world problems today. Added consideration should be given to the important role which the careful and proper use of chemicals plays in increasing the production of healthful and nutritious food from present crop acreage and also to the importance of chemicals in reducing tremendous economic losses which otherwise result from pests, from food spoilage and deterioration of various kinds. Health benefits result from this production of increased quantities of high quality foods, as well as from the chemical control of the spread of disease by insects. Chemicals are used to increase the nutritive value of foods. Technological advantages include greater food accepta-

Dr. St. John Is Executive Secretary,
Food Protection Committee,
National Research
Council



bility due to improvement in texture, flavor or color. Insufficient emphasis has been placed on the food conservation and health benefits which result directly from the use of chemicals in foods. In this modern age of a technologically dependent population, it is essential to formulate policies and procedures for the production of high quality food which will be safe for use and which will promote public health, while at the same time they promote an efficient national economy.

Need and Value of Chemical Additives

What is the need for the addition of chemicals to our foods? Why is it not possible in this modern world to have foods entirely free from added "chemicals"? What are the advantages, nutritional and technological, resulting from the use of "chemicals"?

There is definite need to insure the production of larger quantities of high quality food which will promote public health and vigor. This is further emphasized by present world conditions. Many chemicals have been developed and are used to improve the quality, the nutritive value, the keeping quality and storage life of foods and feeds. Chemicals of various types have long been added to foods to influence favorably the flavor, color and texture, and to make foods more acceptable to the consumer. For many years, research workers familiar with nutritional requirements have advocated an increased intake of certain minerals, particularly calcium, and more recently certain vitamins such as thiamin hydrochloride have been added to some food products, such as

Based on a paper presented before the meeting of the National Council of Farmer Cooperatives in Chicago, January 8, 1951

enriched bread. The enrichment program has received wide publicity, acceptance and approval by those familiar with the situation. Following their identification by the chemist, some nutritional supplements such as thiamin hydrochloride are now prepared synthetically for regular and continuous addition to certain food products.

Such common chemicals as ordinary salt and sugar have been universally used. More recently technological research has advocated the use of some additional chemicals favorably to affect texture and to retard deterioration in order further to conserve present food supplies. Further, in the treatment of goiter, the well-known chemical, iodine, is recommended in small quantities. Fluorine has been recommended in stipulated small quantities for specific purposes.

Man has continuously fought pests and disease. Chemicals have been more recently developed which have been particularly effective in this fight. An extended use of chemicals in this field has provided pesticides to control insect pests on crops and on animals. Some of these chemicals find their way incidentally into food, usually in very small quantities. In many areas of the world the primary method by which the production of essential food can be increased is by increasing the yield of food crops from land already under cultivation. Pesticides which are highly destructive of pests and diseases, and which can at the same time be used with safety to man and animals, are important and effective weapons to help insure the food supplies of the world.

Many of these newer chemicals have already resulted in large increases in production. Control of insects afflicting dairy cattle has resulted in many instances in fifteen to twenty per cent increases in milk production and the addition of as much as fifty pounds per animal to beef animals. The dollar value of these results has been estimated at $100,000,000 per year. The control of grasshoppers in Montana and Wyoming alone resulted in the saving of enough pasture grass to produce 11,000,000 pounds of beef. Seven and one-half million dollars additional income resulted to California growers through protection of the lima bean crop from one insect pest. One fungicide increased the production of Anjou Pears by 300,000 bushels per year. The State of Washington produces more fancy apples than any other state in the union. The national apple crop is valued at $250,000,000 per year. This important agricultural industry is dependent on the use of pest control materials to control insects and diseases. It is imperative to

control such pests by the use of pesticides, or to forego almost completely the production of much of this important fruit.

In North America there are at least 6,500 insect pests which are of economic importance. The estimated damage to food products alone caused by insects in the United States amounts to at least $4,000,000,000 annually. There are about 10,000 plant diseases of economic importance in the United States and these cost the nation about an equal amount. Pesticides are essential to decrease markedly these losses and effectively increase food production.

The Food and Agriculture Organization of the United Nations has focused attention on the tremendous loss in stored food over the entire world caused by insects, fungi and rodents. Stored grain losses caused by insects in the United States alone have totaled approximately 6,000,000 bushels a year. These losses are being rapidly reduced by use of certain chemicals. Effective and safe pesticides are essential to effect a marked reduction in these losses.

Some pesticides are added to soils as an efficient method by which certain insect pests and certain plant diseases can be effectively controlled, and some control measures of this type appear to be essential to food production.

Much evidence has been accumulated by a large variety of dependable research agencies over a long period of years that appears to demonstrate amply that the use of chemical fertilizers is essential to the production of adequate quantities of wholesome food for our increasing urban and our rural population.

It appears that the use of chemicals in modern food production, processing and preservation is essential if we are to produce and preserve a sufficient quantity of high quality food to nourish our increasing population, and thus promote optimum public health. Much evidence has been presented to support this viewpoint.

What Are Chemical Additives?

The Food Protection Committee has proposed the following terminology: "Chemical additives are considered to be pure substances or mixtures of known and reproducible composition not usually present in the particular foods concerned, or present only in suboptimal amounts."

These chemical additives are considered in two groups:

(1) *Incidental Additives* are not introduced into foods by design; they are adjunct substances which remain (usually in small amounts) after usage in food production, processing and storage, such as: (a) pesticides such as insecticides, fungicides, herbicides and rodenticides for field and inside use, including aerosols and fumigants; (b) cleansing agents such as bacteriocides and detergents; (c) packaging materials such as wax coatings, plastic films and resins; (d) plant growth regulators; (e) soil fumigants and seed treatment chemicals, including fumigants.

(2) *Intentional Additives* are adjuvant substances which impart some special quality to the food, such as: (a) nutritional supplements, such as vitamins and minerals; (b) processing improvers, such as flavoring and coloring agents, emulsifiers, sweeteners, maturing and bleaching agents; (c) preservatives, such as antioxidants, mold inhibitors and disinfectants.

In general, we know more about chemical additives than we do about the natural food materials. We know more nearly their exact composition and properties. In some cases we know more about their relative toxicity from carefully controlled research work than we do about the toxicity of natural foods. Much more is known about their relative nutritive value and their indirect effects on nutrition. Also, more is known regarding technological effects on such factors as the appearance, texture, flavor and food acceptability, and, in general, about the benefits derived from the inclusion of the different individual substances in the diet. It is thus possible to refrain from adding to the diet those items known to offer a hazard or to lack benefit or value of some type.

Some individuals have the impression that a "synthetic" substance is undesirable per se. What is a "synthetic"? The protein in plants is synthesized in nature from the nitrogen absorbed through their roots, largely in the form of nitrates, and from other chemical elements obtained from the soil and air. Other food materials are somewhat similarly synthesized by the plant. An animal synthesizes proteins and other constituents of its body, which are later used as human foods, from the feed materials available through its digestive system. Man has learned to duplicate nature in certain respects and to synthesize some inorganic and organic materials in the laboratory.

He has not learned to synthesize all of the complex chemicals which have been synthesized in nature. He can, however, put together in the laboratory some of the building stones of proteins—the amino acids—and thereby synthesize simple proteins. The chemist has also synthesized some valuable products which are not found in nature and new products which are an improvement over natural materials previously used. More striking examples, in the nonfood field, are plastic packaging materials and the nylon type of fabric which seems to be rapidly substituting for the natural products used for the same purposes for generations.

Common salt is largely mined. However it can also be synthesized in the laboratory. The two products, whether secured from salt mines or synthesized in the laboratory, are identical. The physical, chemical and biological properties and the relative toxicity are the same for a synthesized product as for a natural product. In fact, in many cases, products synthesized by man in the laboratory are more pure than those normally secured from natural sources. Thus a "synthetic" is not per se harmful, and the fact that it is synthesized in the laboratory rather than in nature has no relation to its relative safety.

Safety of Chemicals

Are chemicals per se harmful? Or do they, like most things, vary in their potential hazard, depending partly upon their relative toxicity which measures their capacity to cause injury, and partly upon the quantities which remain in the food and upon the quantities which are consumed during a given period. Chemicals may vary greatly in toxicity. Some are considered nontoxic, others are very highly toxic, such as parathion or nicotine or the highly poisonous 1080. Nicotine is said to be one of the most rapid and deadly poisons known to man.

In considering hazards which may result from incidental additives of high toxicity, careful distinction must be made between use hazards and food hazards. In addition to the industrial hazards encountered during the manufacturing process, there may be use hazards which occur during the use and application of toxic pesticides. In general, the use hazards are related to acute toxicity. Pesticides must be handled and applied strictly according to carefully prepared directions based on research which developed protective measures to reduce or

avoid such hazard. Parathion is illustrative of such a pesticide. It must be used strictly according to directions to avoid use hazard.

In general, food hazards are related to the chronic toxicity of a chemical. Toxic chemicals may offer a food hazard if they remain in food in quantities above a maximum limit or "tolerance." It is highly important to determine the quantities in which such chemicals occur in foods and to determine the safe limits which can be permitted. Such limits for pesticides are being determined through the residue hearings which are expected to result in acceptable "tolerances."

Some pesticides may offer definite use hazards related to their high acute toxicity, but in contrast, because of certain properties, may not offer a food hazard. An illustration of this is again found in parathion. It is widely believed that this pesticide does not offer a food hazard since, due to its physical properties, it does not remain on the crop at harvest.

It has been stated that more deaths result each year from the use of nicotine sprays than result from the use of parathion. It has not been considered necessary however to discontinue the use of nicotine sprays. It should be emphasized that these were accidental deaths resulting from exposure during the use of such sprays, and that the use of nicotine sprays has not been considered to offer a food hazard, due again to its physical properties.

Long usage may have demonstrated that a chemical, as well as a natural food, does not offer a hazard when consumed in usual quantities. For illustration, the chemical additives salt and sugar are considered safe. It is believed that these common food materials promote health and well being, although if consumed in excessive quantities or by persons with certain disease conditions, even some of these more common food adjuvants may offer a food hazard. However, there is no recommendation that the use of these chemicals in acceptable quantities should not be continued by normal individuals.

Current Work and Present Safeguards

Many agencies are concerned with the various phases of this important and complicated problem—the insuring that chemicals can be used efficiently to increase and preserve our supplies of high quality food for the benefit of public health, and at the same time insure that

the use of those chemicals which are toxic will not create a hazard which will defeat the beneficial results obtained. Many state and federal research agencies are devoting a comparatively large amount of time to the development of efficient and safe methods of use and application of pesticides which will insure that such use will not create a food hazard.

Regulatory agencies are also doing research bearing on the levels at which chemical additives may be used in foods without harm. Such work is being done by the Food and Drug Administration and by the Insecticide Division of the United States Department of Agriculture. Some state regulatory agencies are developing necessary analytical methods to determine precisely the quantities of chemical additives which are actually present in foods.

Many research agencies are developing additional chemical methods. Several new analytical methods were presented to the Pesticide Division of the American Chemical Society at their Boston meeting. The Association of Official Agricultural Chemists, a national society of long standing, makes a study of chemical analytical methods proposed for the determination of small quantities of chemical additives in foods. Public health agencies, both federal and state, and the American Medical Association are contributing to the solution of the problem, the latter emphasizing use hazards and diagnosis and treatment of accidents occurring during use. Private laboratories are studying the relative toxicity of various chemicals proposed for use in foods.

Chemical manufacturers are continuing to develop new chemicals designed for various uses as both intentional and incidental food additives. Following a determination of the effectiveness of these materials for the purpose for which they are to be used, manufacturers study the relative toxicity of the compounds which prove efficient. They develop methods of use which will reduce or eliminate hazard during application and accumulate information regarding the maximum amount which can be safely used in foods without offering a hazard to health in the case of those chemicals which are toxic.

Much research work has been done by state experiment stations and by the USDA to develop efficient methods for the removal of spray residue from fruits and vegetables after harvest and preceding ship-

ment. Food producers, particularly fruit growers, use these procedures for the removal of spray residues preceding packing and shipment. Commercial residue-removal methods are an advantage in placing on the market a cleaner appearing product which has added consumer appeal. The removal of spray residue from fruits and vegetables is an advantage in the sale of these crops to food processors. Many food processing companies are progressively increasing their emphasis upon the purchase of only those crops from which residue has been effectively removed, since they are aware that they cannot distribute processed food bearing residue detrimental to public health. Leading food industries already have well-established field surveys and analytical facilities, and they determine the residue load before purchase of food crops from the farmer, or, if excessive residues are found on food materials received by the processors, they may be rejected at a financial loss to both the food processor and the farmer.

The farmer also has a direct responsibility in protecting foods from harmful amounts of spray residue, in common with the chemical manufacturers, food processors and research and regulatory agencies. Pesticides must be used according to the recommendations developed by research agencies, and by chemical manufacturers and food processors. Otherwise, excessive residues will be found on foods where pesticides have not been used in the quantities recommended, but in excessive amounts. Some pesticides will leave residues if used too late in the season, contrary to directions. Difficulty may result if pesticides which have not been found efficient and which are not recommended by research agencies are used by growers in an attempt to control pests.

Many laws are in effect, both federal and state, which are designed to insure that chemicals shall not be contained in foods in quantities which offer a hazard to the public health. The Federal Food, Drug, and Cosmetic Act of 1938 requires the establishment of tolerances limiting the amount of essential toxic chemicals which will be permitted in foods. An extensive hearing was conducted by the Food and Drug Administration during 1950 which will form a basis for the establishment of such tolerances. Extensive research information on necessity for use and on toxicity has been presented to the Food and Drug Administration during the progress of this hearing. In addition to the federal food and drug law, some states have spray residue laws. The Food and Drug Administration is authorized by the present law

to establish food standards which may be utilized to regulate chemical additives in foods. During 1950 there was a continuation of the hearings to receive evidence as a basis for the establishment of standards of identity for bread and related products. The data included information regarding the toxicity and safety of additives which have been proposed for approval for use in bread and pastry-type products. In January, 1951, a food and drug hearing was begun to establish standards of identity for ice cream and related products. Among other data, evidence was received on the toxicity and safety of additives proposed for use in such products.

The Meat Inspection Service of the USDA under the Meat Inspection Act regulates the use of chemicals in meats, and has accumulated information regarding the relative toxicity and the relative safety of various chemical additives. From the toxicity data available, both this service and the Food and Drug Administration have classified many chemical additives according to the relative hazard which they may offer if present in meats and other foods. Thus we have a preliminary classification of many chemicals based on the toxicity data available at present. The Insecticide Division of the Department of Agriculture, under the recent act of 1947, has, it is understood, registered approximately 32,000 products proposed by manufacturers for use as pesticides. These are based to a large extent on perhaps 100 to 125 separate pesticidal chemicals. Labels for toxic pesticides are carefully developed in the light of research data available on both acute and chronic toxicity and on effectiveness to aid in avoiding both use and food hazard. These apply to interstate shipment. State laws covering pesticides are in effect in thirty-nine states, many of them based on the uniform state bill. Other states are at present considering legislation.

It is understood that the Food and Drug Administration, the Insecticide Division of the USDA, and the Meat Inspection Service are in frequent consultation. It is understood that each is in frequent consultation with chemical and food manufacturers regarding safety in the use of chemicals which offer promise as both incidental and intentional food additives, since many companies regularly notify these regulatory agencies of their intention to use a new chemical as a food additive. Consideration should perhaps be given to the provision of additional funds for both national and state regulatory work.

The Council of State Governments has prepared a uniform state bill for the regulation of certain hazards during the use of pesticides. This has been approved by several other organizations, including the Association of Economic Poisons Control Officials. The Congressional committee authorized by House Resolution 323 of the Eighty-first Congress has been receiving information to use as a basis for the determination of whether or not there is need for added legislation to protect adequately public health in connection with the use of chemical additives.

The appointment of the Delaney Committee resulted from emphasis by those who feel that there is a need for additional legislation to protect the public health by requiring that all chemicals which are added directly to, or find their way incidentally into, foods shall be adequately checked prior to their use to determine that they are safe for use and that they are not a hazard to public health. Those who advocate added legislation feel that the extensive research in progress and which has been done by state and federal agencies and by industry is not sufficient, and that existing federal and state legislation does not give sufficient authority to protect the public, in view of the rapidly increasing use of chemicals in foods.

Additional Needs

A thoroughly organized plan of attack on those phases of the entire problem which need further consideration should be carefully developed. It is important that a set of guiding principles for the determination of safety in the use of chemicals in foods should be formulated, and so far as this is feasible, that there should be a standardization of those procedures which appear essential to safeguard foods in the interest of public health.

The scientist approaches the problems involved by a fundamental scientific type of attack. It is of primary importance to know how and why materials act as they do when they exhibit acute and chronic toxicity to man and animals and plants. Details of the effect of toxic substances on metabolism should be determined. To evaluate properly the safety of a chemical compound for use in foods, it is necessary to correlate carefully the available chemical, physical, biochemical, nutritional, technological and toxicological knowledge. The basic type of

research aids materially in a more rapid solution of such an important problem. Increased emphasis should be placed upon work of this kind and it should be strongly recommended to various research agencies.

Additional work needs to be done on the development of chemical analytical methods suitable for the accurate determination of minute amounts of additives which may be present in foods. The establishment of "tolerances" is needed to specify and limit the amount of those compounds which are toxic to the quantity which may be permitted in foods, but which still will not offer a hazard to public health. Work is needed to develop further methods of removal of spray residue which remains on crops when it is necessary to use pesticides for the control of insects, fungi and other pests. This is particularly true regarding methods for the removal of spray residue from vegetables, which have received less attention than fruits, to insure that the residue has been removed to a level of safety for consumption.

It seems probable that more information is needed on the effect of some intentional additives on the nutritive value of the foods to which such chemicals are added. We should know the relative nutritive value of the compounds which are added and we should know the effect of their use, if any, on the nutritive value of the final food product. This should perhaps be extended to an investigation of any possible effect of the added chemicals on the physical, colloidal and biochemical properties of these additives on the relative nutritive value of the final food products.

It has been estimated that only about one per cent of the usual diet as actually consumed contains any spray residues. With residue levels below tolerances, the total amount of these incidental additives consumed is very small. Similar consideration should be given to intentional food additives. In evaluating the safety of chemical additives, emphasis should be placed not only upon the research data showing toxicity, but also upon the relative quantities which are found in the food and upon the total amount which may be consumed in the usual diet. It may be considered in the terms of a published statement by a representative of the Food and Drug Administration, that the "situation calls for genuine concern about the future, but not for alarm or hysteria about the present."

Summary

The use of chemicals in food production, processing and preservation has increased recently. Some chemicals find their way into foods in small quantities incidentally, while others are intentionally added directly to foods to improve quality or to increase nutritive value.

There is need to insure the production of larger quantities of high quality food which will promote public health and vigor. Pesticides have been extensively used to increase crop production. Vitamins and minerals are added to diets. Some chemicals improve quality or prevent deterioration. Many chemicals are beneficial, and in some cases they are essential.

Research to prepare new chemicals and to demonstrate their usefulness and safety should be stimulated and well organized. Existing data should be coordinated and critically and impartially evaluated. Practical conclusions should be widely distributed.

Chemicals vary in their toxicity. Some are considered nontoxic while others are very highly toxic. Some chemicals are considered directly beneficial and are recommended in the diet. Others are considered safe for consumption in somewhat larger quantities. Some may cause harm if consumed in small quantities over long periods of time. Acutely toxic chemicals may cause immediate harm if consumed in sufficient quantity. Chemicals should not be considered harmful per se.

Many agencies have been studying many aspects of this problem, since it is important to insure that each chemical added to food is safe for continued consumption, in quantities recommended or permitted, without hazard to public health. **[The End]**

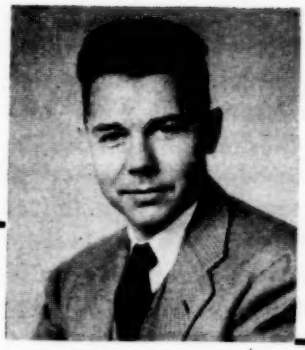
THE NEWEST ANTIMALARIAL, Aralen, has achieved "remarkable results" in suppressing malaria in a heavily infected Belgian Congo village. Small weekly doses "did not seem to create any danger for nursing infants and small children" and reduced infant mortality, according to a report prepared by Dr. C. Dricot, a Belgian. Comparative trials with chlorquanide, were "good but less striking," and, Dr. Dricot said, "quinine suppression has found . . . a rival destined to replace it."

The Food Law Is Reasonable

A "Reasonable" Approach by Business and Government to the Federal Food Law Will Eliminate Most Problems for Both

I HAVE BEEN ASKED to comment on some of the problems that have involved foods during the course of our enforcement of the Federal Food, Drug, and Cosmetic Act. This opens a wide field for discussion, for practically every violation that we encounter constitutes a problem in some degree, inasmuch as no two violations are ever exactly identical. The analytical results will vary, the background of factory inspection evidence will not always be the same, the labeling may be different even on two shipments of a product from the same firm, and the judicial district in which the case arises may not be without effect on the outcome of any action we may undertake. My purpose will be to mention a few types of violations which give us special concern, either because we lack adequate analytical methods to deal with them, or because they require different inspection techniques, or perhaps because we must remember that the law does not require the impossible.

"If the law supposes that, the law is a ass, a idiot," Mr. Bumble expostulated in *Oliver Twist.* To one engaged in law enforcement work, this sounds like the rankest heresy, but what Mr. Bumble was protesting against was not the intent of the law as it was originally enacted, I imagine, but rather the unwise and unimaginative administration of the law. Fortunately, Mr. Bumble was not speaking of the Federal Food, Drug, and Cosmetic Act or its enforcement, but I can well imagine circumstances where, unless the administrative policy was wisely and skillfully formulated, his comment would be appropriate, and would doubtless be made in various Americanized versions. In fact, it is possible, I believe, to stultify any law by unrea-



By L. M. BEACHAM
Chief, Canned Food Branch,
Food and Drug Administration

sonably narrow interpretation and unimaginative enforcement, and conversely, even a poor law can often be wisely administered. Let me illustrate this by considering for a moment a simple traffic sign which I can see from my office window in Washington. It says "stop." Now we who read that sign, motorist and traffic officer alike, understand that it means "Stop and then proceed cautiously." Imagine the traffic jam that would develop and the agonized letters to the editor that would be written if some overly zealous and literal-minded traffic cop should interpret the sign to mean "Stop and remain stopped" and should undertake to enforce his interpretation. Yet that interpretation would be entirely reasonable, and indeed is the prevailing one, at the traffic light a block down the street where a red light reading "stop" alternates with a green one reading "go." There the command to stop obviously means to do so and to remain there until the instructions are changed: until the green light flashes.

"Hidden Infestation" of Grain

I won't labor the point I am seeking to make: the impartial administration of a law need not be synonymous with an unreasonably narrow interpretation of the law without any consideration of collateral circumstances. And that brings me to one of the types of problems I shall talk about. It involves the kind of situation where wisdom, factual knowledge, and administrative ability are required to carry out impartially the intent of Congress without creating situations so unreasonable on their face and that work such hardship on the consuming public as to provoke repeal or amendment of sec-

tions of the Act. The first such situation that comes to mind is one which we are currently studying in an effort to obtain as complete compliance with the Act as we can reasonably require. The question hinges on the degree of freedom from insect contamination that manufacturers of cereal foods can attain in their finished products. The facts are these: the manufacturers of such products as flour, corn meal, or farina can, with conscientious and unremitting effort, maintain clean premises, equipment, and storage facilities. While we recognize that it is not easy, we are convinced that it is possible for mills to operate in such a manner that no filth or other extraneous material is added to the food product during the course of manufacture, and in our enforcement activities we insist that they do so. However, there is one complicating factor not subject to such control. This is the infestation of the grain, wheat, and corn, before it reaches the mill. There are at least three insects, to use the term in a broad nontechnical sense, that infest grain. There are weevils, moths, and borers, all of whom have the unfortunate ability to damage grain in such a way that the evidence of their depredation may not be apparent to the unaided eye. For example, the weevil makes an almost microscopic puncture in the grain and lays her eggs. At some later date, depending on temperature and conditions of storage, a larva hatches out and grows inside the grain. Anyone examining the grain would not be able to distinguish the sound from the punctured kernels. Only when the grain is examined in the laboratory does its true character become apparent. We call this "hidden infestation" to differentiate it from visible infestation where live insects can be seen crawling on the outside of the grain and damage is plainly visible where they have been feeding. Let me make it clear that we feel that there is no excuse for using material of this type in food products. Nor do we condone the use of grain having hidden infestation, but we do recognize that it is far more difficult for the miller to detect and eliminate such grain from his raw material. It is to be hoped that additional research will develop simple, practical, and reliable methods of detecting such hidden infestation, and of separating out the grain so affected from the uninfested residue, but we do not have them at the present time.

So much for the problem; now what is the Food and Drug Administration doing about it? We would like very much to be able to

insist that every shipment of cereal products coming within the jurisdiction of the Act be prepared from grain that is absolutely free from any evidence of insect infestation. But to attempt to enforce such a program at the present time and in the light of the conditions I have just described would produce such chaos in the industry, would result in the destruction of so much food, and might generate so much hostile sentiment, even from those whose interest we are trying to protect, that we must perforce settle for something less. In other words, those who make our policy must not lay our law open to Mr. Bumble's indictment. In order to learn how much less than perfection we must be satisfied with, and how much better than present practice we can justifiably insist upon, we have set up a widespread investigational program with the cooperation of the milling industry. Under it we have selected a large number of mills throughout the country which previous inspections have shown to be operating under acceptable sanitary conditions. Additional inspections are made throughout the period of investigation, which is one year, to be sure that each mill continues to operate in such a manner that no insect fragments or frass is contributed to the finished product during the course of manufacture. At intervals random samples are taken from incoming shipments of raw material to get an idea of how much hidden infestation is actually coming in, in that mill's current receipts. Samples are then taken at various stages of the manufacturing process to learn how much of the infestation can be removed by cleaning processes and how the remainder is distributed between the finished product and any by-products that may be produced.

At the same time we are collecting samples for laboratory examination from the material passing through the important grain markets. This will show us the proportion of corn and wheat coming to market which is free of insect infestation as well as that which contains various percentages of infestation, visibly and otherwise. It will also show the proportion of such corn and wheat that contains hidden infestation, and the time of year and geographical locations where insect infestation reaches its peak. The data from the samples collected in the market place and those taken at the mills will permit a conclusion as to whether there is actually enough insect-free corn and wheat available if millers are able to find it, and will indicate the relative hazards of purchasing grain at different times of the year, from partic-

ular localities, of particular commercial grades, or from different types of storage. We do not think, of course, that even with this information the miller will be able to buy his grain without looking at it, but it may be of substantial help in pointing the way toward selecting better grain for food use, while on the other hand, we will then know pretty well what the best performance is that we can insist upon when the soundest raw material available is used, and we will thus be in a better position to put pressure on those having less satisfactory performance to improve it.

Colored Margarine

Another problem that we are just coming to grips with requires both new analytical and new inspection methods. It was created by the repeal of the taxes on colored margarine and the amendments to our Act transferring responsibility for enforcing among other things the provisions under which colored margarine may be served in public eating places. These amendments provide that:

> No persons shall possess in a form ready for serving colored oleomargarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently . . . or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, . . . unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine or (2) each separate serving thereof is triangular in shape.

There are, according to the best estimates, somewhat more than 500,000 public eating places large and small in the United States, not counting church suppers and Lions' Club luncheons.* To insure compliance with the law it will be necessary for our inspectors to visit these places from time to time. This in itself is a formidable undertaking with an inspection force of approximately 250 men to whom this is only one of many duties. But proper inspection may involve much more than a mere visit. It is true that if signs are posted or the menu announces that margarine is served and the servings are labeled or are in triangular shape, the inspector may conclude that the law is being obeyed and take his leave without more ado. On the other hand, if no notices are posted, and the servings are neither triangular nor labeled as margarine, he must then make an inspection of the product on hand which is "in a form ready for serving." Since it is not possible to tell by organoleptic

examination whether such a serving is oleo or butter, we have sought for and have developed a rapid chemical method for distinguishing between the two. This method is based upon what is called the "Critical temperature of dissolution," and involves a determination of the temperature at which the fat of oleo or butter, when dissolved in certain solvents at elevated temperatures, will begin to come out of solution, rendering the mixture turbid in appearance, as it cools. Solutions of oleo become turbid at much higher temperatures than do those of butter. The method thus gives a rapid and fairly reliable means of determining whether oleomargarine is being served. We have developed a portable kit with the necessary apparatus and reagents for the inspector to run the test right on the premises during the course of the inspection. If the test indicates that oleo is being served as butter, he takes an official sample for laboratory confirmation by the use of more elaborate and more conclusive method of analysis.

So much for demonstrating the violation; however, other problems will arise in connection with enforcing the oleo amendments. Among these will be the question of what constitutes adequate labeling of individual servings, and the matter of oleo in intrastate commerce, to which the provisions of the amendments are specifically extended. These problems can be better discussed by someone more qualified than I to do so, and will no doubt be the subject of a number of clarifying court decisions. Meanwhile we are cautiously undertaking the enforcement of the oleo amendments as another one of our more important duties, expecting to cope with the various problems as they arise.

"Filled Ice Cream"

In the past two or three years another problem akin to that of margarine has developed and the proper solution to it is not yet in sight. This involves the products which, by analogy with filled milk and filled cheese, may be called "filled ice cream." As the name implies, it is a frozen dessert closely resembling ice cream but with all or, more often, a part of the butterfat replaced with other animal or vegetable fats. I suppose it was inevitable that, with the price of butterfat as high as it has been in the past few years, some ice cream manufacturers would be tempted to experiment with the addition of so-called foreign fats in an attempt to lower their manufacturing

costs. The result has been a product indistinguishable in taste and appearance from real ice cream. Manufacture and sale were at first strictly local and even now are largely intrastate, but as always happens under such circumstances, an occasional interstate shipment takes place. When such a product comes within our jurisdiction labeled as ice cream, we can bring action on a simple misbranding charge, alleging that it is offered for sale under the name of another food. But more often it is not actually labeled as ice cream but is sold under some fanciful name that identifies it as a frozen dessert while the appearance of the product, style of package, circumstances of sale, and other factors all suggest that it is ice cream. Or it may be dispensed from bulk containers into cones or dishes in such a way that the retail purchaser has no opportunity to see the labeling, even though it be completely accurate. Without a direct statement regarding the composition of the product, the consumer would, I feel sure, believe that the product was ice cream. The regulatory problem would be simpler if we had a standard of identity for ice cream, for then we could charge that the article containing the foreign fat purported to be a product for which a standard had been made and that it did not comply with the standard assuming the standard banned foreign fat. As it is, we charge adulteration under Section 402 (b) (2) in that another substance has been substituted for the butterfat. An announcement of this policy was published in the *Federal Register* of April 13, 1950, and read as follows:

> The Federal Security Agency has received a number of inquiries regarding proposals to market in interstate commerce a frozen product made in semblance of ice cream, but containing vegetable fats in complete or partial substitution for milk fat. It has been stated that the product is being currently manufactured in several states for distribution wholly within the borders of the state in which it is made.
>
> This Agency regards products of this type, in which any vegetable fat is used as an ingredient, as adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, and therefore subject to action under the law.

Water Added to Canned Tomatoes

A problem that has engaged a substantial amount of our attention in the past two or three years is the resurgence of a practice older than the Food and Drug Act of 1906: adding water to canned tomatoes. We have always regarded this practice as rendering the

product adulterated, and have considered it as an economic cheat without any justification, inasmuch as sufficient liquid to fill the interstices between the solid pieces of tomatoes in the can usually drains from the tomatoes in the course of peeling, coring, and packing, or can readily be obtained from other tomatoes. For many years we rarely encountered interstate shipments of watered canned tomatoes, but recently we have been surprised to find unmistakable evidence during our factory inspections that a number of canneries have been adding water to the liquid packing mediums. Without evidence developed by factory inspection it is difficult to say with certainty that a given shipment is adulterated, solely from the analytical results on a sample of the finished product. To reveal the presence of added water, we rely on a comparison of the immersion refractometer readings, generally called I. R. readings, of the suspected sample with those of an authentic pack of tomatoes put up by an inspector in the same plant at a date close to that when the former was packed. The immersion refractometer is an instrument which measures the amount that a ray of light is bent as it passes through a solution. The bending is dependent on the amount and character of the materials, in this case tomato constituents, which are dissolved in the liquid. Added water diminishes of course the amount by which the light ray is bent. However, not all tomatoes have the same I. R. reading, for it varies rather substantially with variety, location, season, and weather conditions. It is our practice then in plants where we suspect water is being added to have an inspector put up small authentic packs several times during the canning season. These packs consist of several cans of peeled tomatoes taken directly from the peeling tables and placed by the inspector in the cans with only the juice of the tomatoes themselves added. The cans are then sealed and processed under his observation, and are submitted to the laboratory for examination together with samples of the regular cannery output packed at the same time, as well as of that packed just before his arrival and on the previous day. If there is a marked difference between the I. R. readings of the authentic pack and any of the other three samples, we suspect added water and if the same circumstances recur on subsequent inspections, our suspicions become even more strongly rooted. Often these are supported by observations made by the inspector during his factory visit, such as a water hose hanging close by the

juice tank with perhaps tomato material clinging to the end of it, as if it had recently been submerged in the juice; or on occasion we have actually observed an employee adding water to the juice. One ingenious inspector disclosed the addition of water in the following manner. On a summer day when the temperature was approaching 90°, he went into a tomato-processing plant in which he believed water was being added. But his observation showed nothing overt to support his belief. Taking a thermometer from his pocket he took the temperature of several buckets of recently scalded and peeled tomatoes ready for canning. All were well above room temperature. Then he took the temperature of the water flowing from a nearby hose. It was, let us say, 65°. He then placed his thermometer in the tank of juice waiting to be added to the cans: 75°! Therefore, the warm tomato drainings had been diluted with the cool water.

Canned Dried Blackeyed Peas

I will mention another current problem which most of you here in New York may regard as much ado about nothing; but it bothers our southern district offices from time to time. This is the sale of canned dried blackeyed peas under labeling suggesting that the product has been prepared from succulent peas. Many of you are probably not acquainted with that delicacy of the Deep South, blackeyed peas. They belong to the larger family of cowpeas of which more than forty varieties and subvarieties are recognized. Most of these varieties are raised and eaten as fresh vegetables in the South and many of them are canned while succulent. However, it is far more economical to soak up and can the dried peas during the off-season months when the cannery would not otherwise be operating than to try to put up the pack during the brief period in the late summer when the peas are ripe but still succulent. That is the season when other fruits and vegetables must be canned: tomatoes, green beans, peaches, and other vegetables which won't wait. Nevertheless, many canners do not make the necessary effort to can the succulent peas. They feel deeply aggrieved and complain to us when they encounter stiff competition from goods they feel certain have been packed from dried peas, yet which are not labeled to show it. Their complaint is a just one, and the practice constitutes a misbranding, but the truth of the matter is that it is extremely difficult to prove by objective examinations

that dried, rather than succulent peas, have been used. I don't think the matter is of much significance to the average consumer of canned blackeyed peas, or other varieties of cowpeas, but it is an unfair practice against the packer who takes pride in putting up the succulent product. Consequently we are on the alert for better analytical methods of distinguishing one from the other.

Adulterated Canned Shrimp

Let us now discuss a regulatory problem that reached its crisis during the time of the old Food and Drugs Act and of the solution that was begun then and has continued under the present Act. During the early thirties we were encountering a great many shipments of adulterated canned shrimp from canners along the Gulf and South Atlantic Coast. The goods were adulterated either because they had been packed from spoiled raw materials or had been so improperly processed that spoilage had taken place after canning. Here was a serious violation of the law against which nothing short of the most vigorous corrective action would suffice. Accordingly we were forced to seize shipment after shipment until some of the canners were facing bankruptcy. As one can always expect in our democracy when the pressure from a government agency becomes too great, the "pressees," in this case the canners, went to Congress for relief. Congress chose a wise course; it amended the Food and Drugs Act by adding Section 10A, which when the present Act was passed a few years later, was incorporated by reference and later became Section 702a. The amendment provided that the Administration "upon the application of any packer of any seafood for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing and labeling thereof." It further provided that if the food itself and the methods of packing were found to be in compliance with the Act, a statement on the label might be authorized to show that fact. The cost of the service was to be borne by the canners receiving it. Operations under the Seafood Inspection Service began in the fall of 1934. Since I spent a short time in the Seafood Service at its very beginning, I feel rather qualified to describe it.

Our regulations provided minimum requirements for physical equipment in the canneries, including adequate temperature controls

for the processing retorts, minimum sanitary requirements, and among the most important features, an inspection belt for observing and sorting the raw material as it entered the cannery. The inspector was required to be present in the plant at all times when it was operating to insure that the shrimp were always handled expeditiously and under sanitary operating conditions. He was also empowered to reject any proffered deliveries of shrimp which were "filthy, decomposed, putrid or otherwise unfit for food." If the finished canned product complied in all respects with the requirements of the regulations, the inspector was authorized to furnish the packer with a certificate identifying and describing the particular lot of canned shrimp covered. The certificate stated that the goods had been packed under inspection and met all the requirements of the food and drugs Act. A legend was required on the label reading "Production Supervised by the United States Food and Drug Administration." This legend has since been made permissive.

Owing to the conditions of widespread unemployment prevailing in 1934, and in the remaining years before the war, we were fortunate in being able to hire a number of competent and versatile young men, many of whom have remained with us and have risen to positions of importance in the Administration. I use the word "fortunate" advisedly, for there were a number of circumstances connected with the jobs we had to offer to make one think twice before accepting them if other employment had been available. At first we could offer appointments for only six weeks' employment with the possibility that this might be extended. Later we were able to extend initial appointments to six months out of each year and now offer full-time employment. The living conditions were primitive in some of the communities in the marshlands of Louisiana and at other points along the Gulf Coast and the east coast of Georgia and Florida where plants applying for inspection were located and where perforce the inspectors lived. The working hours never failed to astonish the applicants to whom appointments were offered. It had been a custom of many years' standing among shrimp canners to begin operations about two o'clock in the morning. If the amount of shrimp delivered to the cannery was small, the cannery operations might well be completed and the premises cleaned up before the sun peeped inquiringly over the horizon. If the catch had been heavy, on the other hand, the sinking sun would

shine on shrimp glistening as they were still being unloaded from the holds of the fishing boats. During the busiest part of the packing season the inspector's working hours frequently exceeded 100 per week. In slack periods the days when there was little or nothing to do brought the average number of hours worked per day down to a more reasonable figure, but this merely gave point to Mark Twain's oft-quoted remark that "a correct average is a mild virtue in a watch." Despite these adverse conditions, most of our appointees undertook the job with enthusiasm and we considered those who carried it on successfully as showing a promise of future usefulness which, as I have said, later years have fulfilled.

The number of plants that applied for inspection increased from three initially to more than fifty before Pearl Harbor. In 1944, supervisory inspection was extended to packers of canned oysters under regulations closely patterned after those for shrimp.

Sixteen years of experience in conducting the voluntary inspection service has brought up a number of problems that would ordinarily never arise in our regular enforcement activities. For example, the inspector is authorized to condemn any shrimp or oysters in the possession of an inspected plant which are filthy, decomposed, putrid, or otherwise unfit for food, and the operator of the plant is required to destroy such condemned material. Nowhere else do we exercise this authority, the Act providing of course for libel for condemnation proceedings in the federal courts. In the inspection service it has been necessary to approve hundreds of labels, not only as to the inspection legend but also with respect to all other wording or pictorial representations, since the certificate of inspection certifies that the labeling complies with all the provisions of the Act. This is the only instance where we have felt authorized to give official approval to labels: our traditional policy is to offer informal comment on a label in the light of the applicable provisions of the Act, but to leave to the courts the prerogative of deciding whether the label actually complies or not. The certificate itself was a complete innovation, for never before had we given formal assurance that a food product complied with the Act. In this connection it will be of interest to note that a few times we have found shipments of goods covered by certificates which no longer met the requirements of the Act because of spoilage due to faulty seams or for some other reason. We have

taken prompt steps to revoke the certificate and to remove these from the channels of trade just as if they were any other violative shipment in interstate commerce.

The operation of the Seafood Inspection Service has brought a solution to the problems facing the shrimp canners in 1934. Almost immediately, with the inauguration of inspection of raw materials, sanitary operating practices, and adequate and controlled heat processing, the amount of adulterated shrimp packed fell off to almost nothing. As time went on and packers became convinced that it was possible to pack shrimp and oysters that would comply with the Act by following the principles incorporated in our regulations, many of them decided to carry out these principles on their own, foregoing the inspection service and saving a rather substantial item of expense in their packing costs. Most of them have done so with a gratifying degree of success, packing a product that complies fully with the Act. To our way of thinking, this represents the best possible solution to any regulatory problem: teaching and inspiring a manufacturer to conduct his operations in such a way that there is no violation of the law for us to concern ourselves with. **[The End]**

APMA AWARD—The Annual Research Award of the American Pharmaceutical Manufacturers Association was presented April 4 to Dr. Howard A. Rusk, director of the Institute of Rehabilitation and Physical Medicine of the New York University-Bellevue Medical Center, for his contribution to the development of the "third phase of medical care," which is devoted to the care of the handicapped from the time they leave their beds until they are satisfactorily employed. The award, established in 1947, is made "in recognition of the work of an investigator who has made a significant contribution in the field of medicine or the medical sciences."

Problems in Manufacturing Baby Food

By R. K. PHELAN

IN THE EXPERIMENTAL STAGE Are Several Contributions Toward Improving the Preparing, Processing and Preserving Methods in This Important Industry

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THE PROBLEMS of manufacturing fruit and vegetable baby foods cover a very broad field. Many are the same as those of other divisions of the canning industry, but all of them are ultimately related to quality and the producer's effort to present the best possible product to the customer. Under the heading of quality, we are concerned with many factors, the most important of which are contaminants, nutrients, color, taste, and texture; all of these are of vital concern to the manufacturer.

Problem of Contaminants

Contaminants, particularly pesticides, have been and still are the industry's biggest problem in the postwar period. Before World War II, cryolite, nicotine, and arsenates were the commonly used insecticides. Fungicides were not a real consideration. The uses of the insecticides were well known. We were able to determine their residues readily by well developed chemical analyses. What is more, we could usually anticipate their presence and were able, in most instances, to remove the residues completely by proper washing.

This paper was presented at the meeting of the Food Industries Advisory Committee of the Nutrition Foundation in Skytop, Pennsylvania

Mr. Phelan Is Assistant Research Director, Beech-Nut Packing Company

Although the war, as such, had nothing to do with it, there is no question but that during the last decade there has been a tremendous increase in the insect population. Intensive agriculture with larger and larger areas devoted to single crops has been ideal for this increase in insect population. As so often happens in man's conflict with nature, the recent development of organic pesticides has enabled us to combat this increased pest problem so well that greater and greater crops are being grown, but not without considerable difficulty for the food manufacturer. DDT, benzene hexachloride, and the many other new pesticides have been remarkably effective in their special uses, but the use of each one has introduced individual problems of analysis and removal of a magnitude never before encountered in the food plant or laboratory.

Many of the insecticides were introduced only on the basis of their ability to control insects. Frequently, toxicity studies on warm-blooded animals were inadequate, and, certainly, no basic work was done on the persistence of the residues in processing or on methods for their determination in the finished product. A major part of the effort in many laboratories has been and still is the development of really satisfactory procedures of analysis for pesticides in common use. Even now the whole problem of insecticide breakdown products and their possible toxicity has hardly been touched.

Because of the many pesticides, using chemical analyses after the raw materials are in the plant for the determination of contaminants is like looking for a needle in the haystack. With the production department standing by ready and anxious to run the product, the situation

becomes impossible. Effective control had to be brought out of the "fishing-behind-the-net" stage. This means intensive field control and close work with state and other agricultural authorities so that we can anticipate what will be used on the crops under consideration. It is also necessary to follow through with the farmer frequently to determine the amount and timing of the applications of dust or spray. Often the farmer believes that if a little is good, a lot will be much better, with the resulting excessive contamination of the fruit or vegetable. In many instances, it is necessary to set up field laboratories so that samples of crops in the field can be checked before harvest and before the purchase contract is signed. In spite of all these precautions, repeated checking and rechecking by the best available analytical methods can continue to be tremendously time-consuming, but tremendously important.

At this time, consideration is being given to the development of standard methods for the determination of contaminants of a toxic nature by the use of mosquito larvae. These larvae are sensitive to low levels of pesticides, and by proper quantitative dilution an estimate can be made of the amount of pesticide present. It is hoped that standard methods can be devised so that if a product contains excessive amounts of these materials, the larvae will not grow. If it is found that mosquito larvae are sensitive to subtoxic concentrations of all of the pesticides and their breakdown products, it will be a real step forward. Unfortunately, with all biological processes there is a delay during the growing period, so that for good control, field work will still be important.

Practically all of these new pesticides are much more difficult to remove than the prewar kind were. They have an affinity for oils and waxes and, in some instances, are actually physiologically absorbed into the plant tissue. When contained in the body of the vegetable or fruit, they cannot be removed, and, unless they are of a sufficiently low level to be passed, or are of the type that is destroyed by heat, the raw material cannot be used. When the chemical is in the wax, it may be removed by treatment with detergents, solvents, lye, or various peeling methods. These are successful only because the wax and, in some cases, much of the outer surface of the product is removed.

Selenium offers a unique problem since it may appear in foods from both insecticide residues and by absorption from the soil, where it is naturally present. Certain areas in the Rocky Mountain states have such soils, and products, particularly cereals, from these districts should be carefully checked.

Although in the last two years the picture has greatly improved, clearly established tolerances will aid both the farmer and the processor in the solution of their problems. The Food and Drug Administration hearings in Washington, with which many of you are familiar, will ultimately result in tolerances for both the grower and manufacturer that will be reasonable and safe for fruits and vegetables.

The late Dr. J. K. Wilson of Cornell University completed a project about a year ago on the study of the presence of nitrates in baby foods. He found what were apparently large amounts in some beet and spinach products. Although no cases of sickness caused by nitrates in baby food have been reported, nor do any seem likely, there have been reports of methemoglobinemia when very young infants have been fed water from contaminated wells having a high nitrate content. This does not seem to offer an immediate problem to the industry but it is one that should certainly be followed closely by all concerned.

The subject of acceptability of food products is very broad, but with the proper use of a well qualified test panel, the determination of relative acceptability by observation and organoleptic testing is well developed. Even with some of the pesticide contaminants, it is frequently possible to determine their presence by taste.

Color, Taste, and Nutrients

Color, taste, and nutrients are closely related and are all seriously affected by such factors as poor raw material, improper processing, and poor storage conditions.

The plant geneticists are continually working to obtain vegetables of desirable and uniform size, color, and nutritive value. Recently other considerations are of interest, such as the development of a bean plant bearing beans, all of which will mature at approximately the same time. When this is attained, only one picking will be necessary, and it may be possible to harvest the beans mechanically, thereby avoiding the

two or three hand-pickings now necessary. Although great strides have been made, unpredictable variations in color, taste, and nutrients continually appear in the same seed varieties in different areas or in the same area from season to season.

Peas offer a classic example of the ideal handling of a vegetable product. From the time of planting until the product reaches the consumer, the handling is completely mechanized and the control is now perhaps all that could be desired. In areas where the peas can be contracted for, their planting dates combined with heat unit data predetermine the harvesting schedule for the most economical operation of the viner station over the longest time. During the growing period, entomologists sweep the fields with their butterfly nets to determine the presence of insects. Dusting with pesticides is done when necessary, as shown by the content of the sweeps, but only with the full knowledge of the contracting company. The actual day of harvesting is determined by field tests on the tenderness of the peas so that the quality at the viner station can be maintained. Payment to the farmer is made on the basis of the actual weight of shelled peas obtained from the vines he brings to the station, plus a bonus for high quality as shown by the tenderometer. The shelled peas are promptly washed and may be examined for insects before shipment under refrigeration to the processing plant. Here the peas are again washed, inspected, and blanched, and then are graded by specific gravity separations in brine solutions. Processing can be immediate for there is no necessity of further preparation of the raw material.

Even with this excellent procedure and control, many manufacturers prefer to pack something less than a season-to-season inventory. Here bulk freezing of the prepared vegetable is a desirable means of storage before the processing at a later date. Vacuum freezing, now sometimes called dehydrofreezing, offers an opportunity to freeze such products in bulk and, where necessary, to blanch them before freezing. The individual character of the vegetable particle is retained, which permits accurate weighing, convenient packing in bulk, and easy thawing. This freezing of the product by removal of its own water reduces the moisture content, but this is not undesirable for it slightly reduces the weight to be stored. The water is regained by addition when the vegetable is processed.

Texture

The fine texture of the pureed or baby food is, of course, important, but we could learn more by medical research on the actual assimilation of these foods. Straining, comminuting, and homogenizing are all in common use as the means of reducing the particle size to obtain the desired texture. These operations may be varied from product to product, depending on which gives the most desirable finished texture and the most economical operation. In the past, desirable nutrients have been unintentionally removed by straining. Some work has been done with supersonic sound waves and, in some instances, a fine smooth texture is obtained. The difficulties with this supersonic equipment have been that the power required is much more than that for other types of equipment, and that there is also a potential danger to the operator. In principle, the method is excellent for the tissue is reduced by action on itself in the absence of air.

Fruit Products

Dealing specifically with fruit products, their actual nutrients leave a great deal to be desired. Vitamins and minerals are present here to a much smaller extent than in other portions of a balanced diet. The fruits do offer some calories and, in instances where babies will not accept enough calories from normal sources such as cereals, additional fruit may be given.

Fruits, singly or in combination, are offered by all the well-known baby food manufacturers and they represent about forty per cent of the total baby food business. The reason, of course, for their wide acceptance is their palatability. In addition, they are very desirable as a low calorie dessert. There is one nutritional factor that we have never heard discussed at any of these meetings, which might be called a persuasion factor. Many babies have been greatly benefited by the nutritive content of a spoonful of cereal or liver concealed under a dab of fruit as it enters the baby's mouth. Fruit baby foods do make the total diet much more palatable and are important for this reason.

The fruit products which we are discussing do not include citrus juices. It has been considered, from time to time, that it might be desirable to increase their Vitamin C content. This would mean the

addition of synthetic Vitamin C to the point where applesauce, and perhaps some other products, would compare favorably with orange juice as a source of this vitamin. Although this possibility has been under consideration for some time now, it has never been accepted by the medical profession as being necessary for the public health. The wide use of orange juice in families using prepared baby foods indicates that this is not required. What is more, most manufacturers shy away from products in the special diet food classification.

Great strides have been made in the technology of processing fruits and vegetables for baby food by the establishment of plants on the West Coast. With the famous California sun and seasonal variations in the valleys, a long packing season for many products is assured. Of greater interest is the result of the continuous sun plus irrigated agriculture in the coast states, a combination that goes a long way to assure a crop of uniform size and quality. This, along with genetically improved seed for vegetables, has made possible consistently better raw material for the producer. The technologist can accurately adjust his preparation equipment to handle uniform fruits or vegetables, thus greatly reducing waste and increasing efficiency. In connection with the spray residues, this uniform good quality makes an even surface, which greatly facilitates the preparation of a product that is substantially residue-free.

Bud Dormancy

Looking further into the future, research is pointing toward some rather dramatic contributions to the food field. Fundamental work on bud dormancy is in its third year at the University of Rochester. This research has shown that specific chemical factors control the breaking of dormancy. If such factors can be isolated and ultimately regulated in the orchards, premature blossoming of fruit trees may be prevented. This will be of importance, particularly with apple and peach crops, which now are often in short supply because of late frosts.

"Embryo Inhibiting Factor"

Another factor receiving some consideration at this time is the "embryo inhibiting factor." If such a factor could be used to prevent seed formation, the resulting fruit would be much more easy to pre-

pare in the processing plant. This would also apply to vegetables such as squash, but with fruit and some vegetables its value would be tremendous. A string bean without seeds would be very desirable.

We have recently read a letter from a well-known plant geneticist in which he discusses the desirability of the nutritional improvement of such products as tomatoes. What he says applies to all crops and not just to tomatoes. We quote as follows:

> What I would like to see is for canning companies to pay for the material in proportion to its food value and not in proportion to tonnage, though I realize that will have to be the result of a major revolution. As long as the tomato variety with the double Vitamin C content is paid for at the same rate as the other varieties, with less than half that content that produces ten per cent more yield, they are not going to have a stimulating effect on breeding for high food quality.

The public finally decides what will be produced and is becoming very nutrition-conscious. I believe that the day which this geneticist is hoping for is in the near future. At least one product is now being nationally advertised on the basis of its naturally high vitamin content.

Containers

The most desirable containers are still a matter of considerable discussion. Great progress has been made with containers since the time I wrote by bachelor's thesis on the contamination of cans by leakage in cooling canals. In very recent months the use of radioactive carbon dioxide has thrown considerable light on the causes of food discoloration on storage. By this technique, minute amounts of gasses may be shown by the use of a Geiger counter to penetrate the container to the head space above the product. By other means it can be shown that oxygen in this head space will cause discoloration. It is interesting to note that, although this program is still in an early stage, we have been mistaken in relying only on the vacuum gauge for an indication of the container's ability to prevent the passage of gasses.

In closing, it must be brought out that no attempt has been made to cover all problems of the industry or even all the important ones. These which have been discussed are thought to be of at least general interest to this group. The problems of the industry will continue to be to seek the best possible raw materials, to prepare and process them by the best methods, and to seek to preserve them in the most desirable container. **[The End]**

Sections 402 (a) (3) and 402 (a) (4) Require:

Keeping Food Clean

By H. G. UNDERWOOD

Industry Activities and Regulatory Efforts Have Brought Improvement in the Sanitary Quality of Prepared Foods

IN APPROVING the Food, Drug, and Cosmetic Act on June 25, 1938, Congress reaffirmed the principle that consumers are entitled to pure, clean, uncontaminated food. This Act defines a food as adulterated if, among other reasons:

"Section 402(a)(3)

". . . it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

"Section 402(a)(4)

". . . it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

The Federal Food and Drugs Act of June 30, 1906, dealt with the general problem of filth, decomposition and sanitation only to the extent that in Section 7 a food was defined as adulterated "if it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance. . . ." While this provision is embodied in Section 402(a)(3) of the 1938 Act, Section 402(a)(3) goes further by employing more effective language and by adding the proviso: "or if it is otherwise unfit for food." Section 402(a)(4), however, is the most important and far-reaching addition in the new law applicable to the field of sanitation. This section, which has greatly widened the scope of consumer protection, brings under regulatory control insanitary conditions in food factories which may cause a food to become filthy or to be rendered injurious to health. In like manner, it regulates the sanitary conditions under which foods may be transported and stored.

Mr. Underwood Is a Food and Drug Officer

The Food and Drug Administration has always based its regulatory activities under Sections 402(a)(3) and 402(a)(4) on its interpretation of Congressional intent and its evaluation of the relative importance of violations under these sections in terms of consumer interest and protection. There have been a number of interpretive court decisions, however, under the 1906 and 1938 acts, which serve as a further background for the enforcement policies of the Administration. Those interested may review the numerous decisions in *Decisions of Courts in Cases Under the Federal Food and Drugs Act,* compiled by Mastin G. White and Otis H. Gates (United States Government Printing Office); *Federal Food, Drug, and Cosmetic Act, 1938-1949,* by Vincent A. Kleinfeld and Charles Wesley Dunn (Commerce Clearing House, Inc., 1949); and current decisions appearing in the FOOD DRUG COSMETIC LAW REPORTS.

The careful and prudent manufacturer, however, does not need to have a detailed knowledge of the numerous interpretive decisions, since he will rarely, if ever, run afoul of the law if he exercises proper care in his selection and processing of raw materials and maintains a sanitary plant.

The food industry, by and large, has long recognized its obligations to the consuming public. The active support of leaders in industry materially assisted the passage of the 1938 law. Industry, too, has been sympathetic with the enforcement policies of the Food and Drug Administration under the new law. It is a tribute to the combined efforts of government and industry that the sanitary quality of the American food supply equals or exceeds that of any other country in the world. There will always be a minority fringe, however, who

through ignorance, for monetary gain, or for other reasons will persist in violating the law.

Throughout the history of federal food regulation it was assumed that contamination of food with filth, or decomposition of food, which occurred during transportation from one state to another or at destination could be controlled under the 1906 act and under the 1938 Act in its original form. In September, 1946, however, the Ninth Circuit Court in *U. S. v. Phelps-Dodge Mercantile Company,* [CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7023], ruled in a seizure action that a food product which had become contaminated by rodents while held in original packages in the claimant's warehouse after transportation in interstate commerce was not subject to regulation under the Act because it was not shown that the food was adulterated when introduced into or while in interstate commerce. The Supreme Court was requested to review the case. On February 10, 1947, certiorari was denied and protection of consumers from terminally adulterated food was not possible under the Act until its amendment almost two years later.

Miller Amendment

On June 24, 1948, Congress, in passing the Miller Amendment, amended Sections 301(k) and 304(a) of the Food, Drug, and Cosmetic Act to make it crystal clear that the government has jurisdiction over products which become adulterated or misbranded while held for sale after interstate shipment. This amendment was of utmost importance to consumers in the food field because it restored control over food stored under insanitary conditions following shipment in interstate commerce. The numerous seizures immediately following passage of the amendment brought about prompt correction of insanitary conditions in many warehouses.

That the Food and Drug Administration considers Sections 402(a)(3) and 402(a)(4) to be of great importance to consumers is evidenced by the fact that approximately eighty per cent of the seizures of foods, and approximately seventy-five per cent of the prosecutions filed during the fiscal year 1950 based on foods, involved charges under these sections. That the courts have likewise placed great importance on the consumer-protective potentialities of these sections is reflected in such pronouncements as the following excerpt from a district court

decision in a bakery case: ". . . if he (the operator) can't get the plant in satisfactory condition he must close it . . . . This is a statute that must be enforced for the protection of the public, and where the public interest conflicts with the interest of the plant, then the public interest is paramount."

Contrast in Penalties

It is interesting to study the penalties assessed in prosecutions based on filth or decomposition or insanitary factory practices as compared with all other types of food violations. There is a general tendency to assess greater penalties under Sections 402(a)(3) and 402(a)(4) than under the other sections of the Act dealing with foods. Of the cases terminated in fiscal year 1950, forty-three per cent of the violations under 402(a)(3) and 402(a)(4) were terminated with fines of $500 or more, while only twenty-seven per cent of other types of food violations resulted in fines of that amount. The average fine under Sections 402(a)(3) and 402(a)(4) during the fiscal year 1951 was $622 as compared with $586 for other types of food violations. The latter average is higher than usual because of the termination of a series of olive oil cases in New York, which resulted in several fines of $1,000 and one of $13,000.

One cannot escape concluding from the record of penalties assessed that the courts consider violations involving insanitation, filth or decomposition as being among those of the highest importance from the standpoint of public interest. The size of the penalties and the pronouncements of the courts have gone a long way toward bringing about real protection from the standpoint of sanitary production and storage of foods.

Foods "Unfit" and "Injurious"

The elements of proof of unfitness for food or harmfulness to health are not necessarily involved in violations for foods which are filthy, putrid or decomposed, or which have been prepared under insanitary conditions. The courts have uniformly held that Congress clearly intended the clauses "or if it is otherwise unfit for food" and "whereby it may have been rendered injurious to health" should enlarge rather than restrict the class of foods subject to regulation.

The first interpretive case (*U. S. v. 1375 cases of Tomato Paste* (DC Conn., 1942) [Kleinfeld and Dunn, *Federal Food, Drug, and Cosmetic Act, 1938-1949*, p. 13]) on this point was concerned with a seizure of tomato paste on the ground that it consisted in whole or in part of a decomposed substance. In that case the court held the first clause of Section 402(a)(3) plainly banned all foods consisting in whole or in part of any decomposed substance, and the second clause went on to ban articles which were unfit for food for any other reason. Also in *U. S. v. 184 Barrels Dried Whole Eggs*, 53 F. Supp. 652, (DC Wis., 1943) [Kleinfeld and Dunn, *Federal Food, Drug, and Cosmetic Act, 1938-1949*, p. 59] the court ruled that the Act must be construed to prohibit the interstate shipment of food when it consists in whole or in part of any filthy, putrid or decomposed substance, irrespective of whether it is unfit for food or injurious to health. Other courts have ruled to the same effect.

A number of regulatory actions have been brought under the 1906 and 1938 acts on the basis that the foods were in fact unfit for food or dangerous to health. Perhaps the most dramatic case occurred thirty years ago when commercially canned ripe olives contaminated with clostridium botulinum caused the death of a number of consumers. Recently, however, instances have occurred where cheese manufactured under insanitary conditions became contaminated with microorganisms which caused extensive sickness among consumers. A few years ago cheese made from unpasteurized milk which had been produced under insanitary conditions caused outbreaks of typhoid fever. Early in 1945, a series of outbreaks of food poisoning in two adjoining states was traced to Colby cheese. The victims exhibited symptoms typical of salmonella infection and the cheese was found to be heavily contaminated with salmonella typhimurium. The cheese had been marketed even though the cheese maker had removed a dead mouse from the vat during its manufacture. Bakery products of the cream-filled type have been the causative agent in a number of food poisoning outbreaks. Although usually no interstate traffic is involved, the Food and Drug Administration routinely investigates such cases. In two recent outbreaks, however, interstate shipments were involved and prosecutions under the Act were successfully concluded.

Meaning of "Filthy, Putrid, and Decomposed"

The terms "filthy, putrid, and decomposed" have been interpreted by many trial courts but only a few interpretations of these terms are to be found in decisions of the higher courts. Presumably this is true because the terms of the law are so plain that there has been little occasion for the higher courts to speak on the subject. In numerous decisions under the 1906 and 1938 acts the courts uniformly held that the terms filthy, putrid and decomposed should be given their common and usual meaning. The courts have observed, however, that these terms must be given a reasonable construction in order to carry out the intent of the statutes. Decomposition in a technical sense begins the moment that animal or vegetable life is extinct.

From a legal standpoint, however, decomposition means more than onset of decomposition. As one circuit court stated, "it means a state of decomposition." Also, in many instances it is commercially impracticable to produce and market foods which do not contain some minute particles of filth. In applying the sections of the Act under discussion, the Food and Drug Administration always has and will continue to apply the yardstick which consumers would apply in recognition of the impossibility of absolute perfection in preparing food either in the home or factory. The degree of decomposition or filth considered necessary to warrant actions based primarily on a charge under Section 402(a)(4) inevitably is tied in with what consumers would regard as practical considerations of good manufacturing or production techniques.

Concealment by Processing

It is not required that a showing be made that the food as marketed is organoleptically obnoxious or is perceptibly filthy to the consumer. If filthy, putrid or decomposed materials are used in the production of a food and their use is masked by processing, the food is just as much in violation of the law as though the obnoxious character carried through so as to be readily perceptible in the finished product. In fact, courts have observed that the consumer ordinarily requires no governmental aid to protect him from the use of food products the adulteration of which he can see, taste or smell, but he needs protection from concealed filth or decomposition. Thus, a filthy or decomposed food treated by processing, filtering, sifting, etc.

so as to remove only the readily detectable evidences of filth or decomposition nevertheless would be adulterated under the law. This was made clear under the 1906 act in 1913 when the appeals court (*William M. Galt and Company v. U. S.*, 39 D. C. App. 470 (CA of D. C., 1913)), in a case involving flour contaminated by insects, stated in part: ". . . this flour was not to be fed to swine but was to be sold for human consumption. Even conceding that the worms, insects and beetles could be separated therefrom, the flour would still be contaminated by reason of its contact with them, and it would still contain more or less husks and excreta from the worms, i. e. it would still be filthy within the meaning of the Act."

An interesting decision under the 1938 law is that of the Circuit Court of Appeals for the Fifth Circuit in a seizure action directed against filthy packing-stock butter intended for use in the manufacture of processed butter (*Cloverleaf Butter Company v. U. S.*, 148 F. (2d) 365, 326 U. S. 752 (1945)). Although it was brought out that during the renovating process packing-stock butter is washed and otherwise treated so as to remove evidence of filth, the court stated in part: ". . . it was certainly not intended by Congress to leave packing stock butter manufacturers completely free to use in making their completed product any kind of filthy and putrid material they chose to use, in the faith, the substance of things hoped for, the evidence of things not seen, that, in homely phrase, it will all come out in the wash." The principle embodied in these two decisions has been sustained in many of the decisions under the 1906 and 1938 acts.

Many inspections made by the Food and Drug Administration before passage of the 1938 Act disclosed insanitary conditions which would leave little doubt that filth would most likely find its way into the finished product, but examination of samples taken from interstate shipments did not furnish proof that filth had contaminated the product. The legislative history clearly shows that Section 402(a)(4) was intended to take care of just such instances as these and thus to remedy one of the major inadequacies of the 1906 law. During the Congressional hearings, Mr. Campbell, then Chief of the Food and Drug Administration, pointed out that this section would cover "those instances where food had been prepared under objectionable and thoroughly insanitary conditions, even though you could not find, upon objective examination of the samples, the evidence or definite proof of that filthy condition."

This section demonstrates practically unanimous recognition by the Congress and the public of the need for sanitation in the production of our nation's food supply.

Sections 402(a)(3) and (4) also have a direct bearing on the condition of the raw materials received and used, even though the sanitary condition of the premises of the manufacturing establishment may be otherwise beyond reproach. Action is possible, with proper factory evidence, in those instances where obviously filthy raw material has been manipulated so that the food produced contains filth in a form which cannot be detected by available objective tests. Examples would be butter oil made from cream or butter containing substantial insect filth, cider pressed from wormy apples, and vegetable oils pressed from heavily insect infested and rodent contaminated seeds and nuts.

In adversely passing on a motion for permission to reprocess butter, seized because of filth, into butter oil, the court, after being appraised that there is no known method for removing soluble insect fats from butter oil, stated in part:

> I feel that I am bound by the verdict of the jury to conclude that insect fat is present in the butter in substantial measure. Whole insects, maggots, and fly eggs were in the cream. It was subjected to heating, agitation, and filtration under pressure. It is hardly reasonable to suppose that soft bodies, made softer by the application of heat, would not be crushed by the mechanical processes of filtration. Since the butter fat passed through the filters, it is an inescapable conclusion that insect fat also passed through.

This opinion expresses a judicial view of the legality of an article which would likely contain a form of filth that would be difficult, if not impossible, to detect by available methods. In applying Section 402(a)(4), it is not necessary to establish by objective examination that the food has in fact become contaminated as a result of having been manufactured under insanitary conditions. The fact that insanitary conditions existed whereby it "may have" become contaminated is sufficient.

Determining Methods

The only method of fully determining sanitary conditions under which a food is manufactured is a comprehensive inspection of the manufacturing establishment. A factory inspection is also valuable in determining whether the product is filthy, putrid or decomposed, but in those areas we also have access to many scientific laboratory methods designed to reveal the existence of filth or decomposition.

In the case of decomposition, a determination of one or more of the products of decomposition may yield conclusive evidence that the food itself is decomposed. For example, butyric acid is formed when cream decomposes. Since there is no butyric acid in fresh cream, the finding of a significant amount of butyric acid in a product such as butter made from cream is conclusive evidence that the cream was decomposed, even though the butter may show no organoleptic evidence of such decomposition. In the case of cream, the occurrence of any amount of butyric acid is indicative of decomposition. Other indices may occur in small amounts in the undecomposed natural materials and it is therefore necessary to determine in advance by proper investigational methods the level of the index necessary to demonstrate decomposition. For instance, water-insoluble fatty acids (WIA) occur in small amounts even in the freshest cream. It is therefore necessary to show in using this index that the WIA in the finished product exceeds that which may be normal to undecomposed cream.

Analytical methods for determination of filth frequently involve a separation from the food of minute fragments of insects, rodent hairs, rodent excreta, etc. The presence of such fragments is an index that rodents or insects did contaminate the product.

Investigatory Activities

Before inaugurating court action involving filth or decomposition based on purely objective sampling of a food as shipped in interstate commerce, investigations are required to show the degree of freedom from filth or decomposition which can be expected in the food when manufactured under sanitary conditions and from materials available to the prudent manufacturer. Such investigations are a part of the normal routine of the Food and Drug Administration. Illustrative is the work now underway on flour and corn meal. The work on wheat and flour was described in an article by J. O. Clarke in the May, 1950 issue of the Food Drug Cosmetic Law Journal, while the investigational program for corn meal is described in an article by George P. Larrick in the July, 1950 issue of this Journal. The results of these investigational activities are usually published in a scientific or technical journal.

A brief reference to several typical investigations conducted by the Food and Drug Administration should be of interest to those concerned with Section 402(a)(3) and (4) violations.

For decomposition, the pioneering work in correlating laboratory methods with field studies was first carried out in the early 1900's by the late B. J. Howard, then head of the Microchemical Laboratory of the Bureau of Chemistry. Howard developed a method for estimating the amount of mold in comminuted tomato products such as puree and catsup. The mold count technique applied to processed tomato products not only shows that decomposed material was present in the comminuted products when processed by heat, but also gives a measure of the amount of decomposed material present. The Howard mold count method was first published in 1911 in *Bureau of Chemistry—Circular No. 68.* Investigations under factory conditions demonstrated that with proper care in removing rot from the raw stock, mold counts would be low.

The mold count technique has been adapted, with a background of field studies covering good packing practices, to a number of foods other than tomato products. The seventh edition of the *Methods of Analysis of the Association of Official Agricultural Chemists* also contains mold count procedures for butter, frozen strawberries, pureed infant foods, citrus juices, cranberry sauce and combination foods such as pork and beans containing tomato sauce.

Probably the widest application of the mold count method other than to tomato products, has been to butter. J.D. Wildman adapted the mold mycelia count method to butter. Extensive field studies carried out by Wildman and R. L. Vandaveer in 1938 and 1939 demonstrated that while all butter made from decomposed cream would not necessarily have a high mold count, a high mold mycelia count in butter shows conclusively that decomposed or unfit cream was used. This work is reported in 23 *Journal of the Association of Official Agricultural Chemists* 693-709 (1940).

We have already referred to the use of water-insoluble fatty acids and butyric acid as indices of decomposition in cream and butter. It is not within the scope of this limited article to discuss the details and conclusions reached by the various investigators who studied this problem. Those interested in obtaining a picture of the extensive in-

vestigations necessary to establish the value of these two indices of decomposition will want to read the series of papers appearing in the *Journal of the Association of Official Agricultural Chemists,* reporting the work of Hillig, Ahlman, Lepper and Patterson. (Vol. 31, pp. 739-749 (1948); Vol. 31, pp. 750-760 (1948); Vol. 32, pp. 731-745 (1949)).

Advances Since 1938

While methods for the detection and determination of filth in food products have been studied and developed over a period of many years, the period of greatest development has been during the years following the passage of the Food, Drug, and Cosmetic Act. Chapter 35 of the seventh edition of the *Methods of Analysis of the Association of Official Agricultural Chemists* is devoted entirely to the isolation and estimation of extraneous materials in foods. When we realize that the numerous methods set forth in the thirty-seven pages comprising this chapter were largely perfected in the period since 1938, the conclusion can be drawn that food enforcement officials have taken positive steps to be able to back up regulatory actions with positive proof of contamination with filth or decomposition, even where inspectional background under Section 402(a)(4) would be convincing. There are, however, many problems involving filth and decomposition which remain unsolved. For example, the detection and estimation of soluble filth, which is particularly bothersome, offers a real challenge to investigators in this field.

Industry too is aware of its obligations to produce foods of acceptable sanitary quality. Many organized industry groups have made extensive efforts to effect basic corrections of objectionable conditions and practices. Some industry groups have conducted sanitation schools and employ sanitarians to keep their industry members sanitation conscious. The dairy, baking, confectionery, canning and milling and other industry groups have constantly stressed sanitation in group meetings as well as in the trade press.

In summary it can be stated that industry activities, coupled with concentrated educational and regulatory efforts, have brought about continued improvement in the sanitary quality of prepared foods.

[The End]

Procedure in California . . .

California's Pure Food and Pure Drug Acts, Though Similar to the Federal Act, Have Some Vital Characteristics of Their Own, Procedural and Remedial

MY SUBJECT concerns the procedural and remedial aspects of the state food and drug acts. It should be pointed out now that there is not one state act known as the Pure Food and Drug Act, but two separate acts, one dealing with drugs and devices and known as the Pure Drug Act and the other dealing with food and known as the Pure Food Act. Both of these acts are incorporated in the Health and Safety Code. The procedural provisions in both acts are identical, with a few minor exceptions. For the purpose of our discussion, there are numerous statutes and code sections relating to foods and drugs which are not found in either the food act or drug act. For example, some of these particular acts relate to food processing and food processing establishments,[1] canneries,[2] cold storage,[3] food containers,[4] horsemeat,[5] olive oil,[6] food sulphurs,[7] restaurants,[8] walnuts,[9] bakeries,[10] etc.

In addition there are many other provisions which are found particularly in the Agricultural Code relating to the production and marketing of agricultural products, slaughtering of animals and poultry, production, inspection, storage and marketing of meat and the production, processing, labeling, and advertising of dairy products and imitations and substitutes such as oleomargarine and cheese substitutes. With reference to drugs, you should also bear in mind the provisions of the State Narcotic Act,[11] the Dangerous Drug Act,[12] which regu-

[1] California Health and Safety Code, Section 28289.
[2] Footnote 1, Section 28360.
[3] Footnote 1, Section 28110.
[4] Footnote 1, Section 28335.
[5] Footnote 1, Section 28015.
[6] Footnote 1, Section 28475.
[7] Footnote 1, Section 28500.
[8] Footnote 1, Sections 28600-28665.
[9] Footnote 1, Sections 28330-28345.
[10] Footnote 1, Sections 28190-28254.
[11] Footnote 1, Sections 1000-1797.
[12] Footnote 1, Section 29010.

• • • By BAYARD RHONE
Deputy Attorney General
California

lates the possession and distribution of hypnotic and sedative drugs, the Poison Act,[13] and the Pharmacy Act.[14] The Federal Food, Drug, and Cosmetic Act covers cosmetics as well as foods and drugs. There is no state cosmetic act.

This discussion will be limited to remedial provisions of the Pure Drug Act and the Pure Food Act. The remedies under the two acts are identical, and therefore, in order to simplify the discussion, they will be considered as one act.

Ever since 1907, the state acts have been somewhat similar to the federal statutes. But when you get down to specific cases you will find there are many differences.

Generally the state act is broader and more comprehensive than the federal act. This is particularly true with reference to advertisements. In the state act there are various sections relating to, and prohibiting, false advertising. In considering whether an article is misbranded, all representations and all advertising as well as the labeling may be taken into consideration under the state act.[15] I do not mean to infer that the federal statutes do not prohibit false advertising; on the contrary they do, but the enforcement of the law on false advertising is placed in the Federal Trade Commission rather than in the Food and Drug Administration.[16] In the state Pure Drug Act there are numerous positive prohibitions on advertising. For example,

This article was presented as a paper before the Panel on Food, Drug and Cosmetic Law at the Meeting of the State Bar Association of California in Los Angeles

[13] Footnote 1, Sections 20700-20808.
[14] Business and Professions Code, Sections 4000-4256.
[15] Footnote 1, Section 26209.
[16] *Kordel v. U. S.*, 335 U. S. 345.

it is unlawful to represent that a drug or device has any effect on about fifty named diseases or ailments.[17]

The violation of the state act is a misdemeanor. The procedure with reference to such prosecution is exactly the same as any other misdemeanor and, therefore, no further discussion of that phase is warranted. The principal enforcement agency is the Bureau of Food and Drug Inspections of the State Department of Public Health. The inspectors from this department file innumerable complaints with the various district and prosecuting attorneys throughout the state. You should bear in mind that, in addition, complaints are also filed by city and county inspectors and to some extent by health officers.

One of the outstanding features of the state Food and Drug Act is the provision relating to hearings before the bureau. This is not a hearing as provided under the Administrative Procedure Act for the revocation or suspension of a license. Whenever evidence indicates that adulterated or misbranded foods, drugs or devices have been on sale in this state, the chief of the Bureau of Food and Drug Inspections or the chief of the Division of Laboratories shall make a certificate of the facts as found.[18] The facts stated in this certificate are prima-facie evidence of such facts. [19] Thereupon notice, together with a copy of the certificate of the findings, shall be furnished to the party or parties from whom the food, drug or device was obtained or who executed the guarantee and a time and place shall be set for a hearing.[20] The hearing shall be held at such place as the board or persons conducting such hearing may designate. The hearing shall be private and confined to the consideration of facts. It is also provided that no publication of the facts found shall be made until the conclusion of the hearing. Parties interested may appear in person or by attorney and may propound questions and submit oral and written evidence to show any fault or error in the findings made by the state laboratory.[21]

I am informed that over ninety per cent of the violations and particularly those relating to labeling are corrected as a result of these hearings, and normally the matter is then closed without being referred to the district attorney or prosecuting attorney. The advantages to a private practitioner of this proceeding is immediately obvious because it often provides a method of solving a problem without adverse

[17] Section 26271; *Nesler v. State*, 70 Cal. App. (2d) 202.
[18] Footnote 1, Section 26338.
[19] Footnote 1, Section 26339.
[20] Footnote 1, Section 26340.
[21] Footnote 1, Section 26341.

publicity to the client as the law specifically provides that the hearing shall be private.

At the conclusion of the hearing, the facts may be certified to the district attorney.[22] Although the law specifically provides for a hearing of this nature, the hearing is not a prerequisite to any prosecution for any violation.[23]

Quarantine of Adulterants

The final procedural aspect I will discuss relates to the quarantine of material and proceedings to condemn or release adulterated foods, drugs or devices. Whenever an agent of the board finds or has probable cause to believe that any food, drug or device is adulterated or so misbranded as to be dangerous or fraudulent, he shall detain and quarantine the article and place on it appropriate warning notices to all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the agent or by the court.[24]

It is a misdemeanor to violate such quarantine orders.[25] If the particular article under quarantine ties up valuable space, permission may be secured in writing to remove the article under quarantine to some other specified location. If the article cannot be salvaged, reprocessed, or the defects corrected economically, frequently it is voluntarily destroyed with the consent of the bureau without filing any proceedings in court. If the violation consists of the misbranding or some other matter that can be corrected, usually the bureau permits the making of the correction and after the correction has been made, the quarantine is released without proceedings in court.

Proceedings which are brought are *in rem* proceedings in the superior court in the county or city and county where the article is detained or quarantined, and are brought in the name of the People of the State of California against the offending article. Upon the filing of the petition, the clerk of the court shall fix a time and place for the hearing and cause notices to be prepared notifying all persons who may claim an interest in said article of the time and place of the hearing. A copy of the petition and notice must be posted for fourteen days in three public places in the town, city, or city and county where the court

[22] Footnote 1, Section 26342.
[23] *U. S. v. Morgan*, 222 U. S. 274; *U. S. v. Dotterweich*, 320 U. S. 277.
[24] Footnote 1, Section 26360.
[25] Footnote 1, Section 26362.

is held and in a conspicuous place where such article is detained or quarantined. A copy must also be served upon each person in possession of the article and upon each owner or claimant whose name and address is known. Service may be made by personal service or by registered mail. At any time prior to the date of hearing any person in possession or any owner or claimant may file an answer and request that the article be released.[26]

If the bureau does not file a proceeding within thirty days after detention or quarantine, then the person in possession of the article or any owner or any claimant may commence a proceeding in the superior court by petitioning the court for a judgment to release the article. The provisions for notice in such event are almost identical as in the case where the proceeding is brought by the people.[27]

Regardless of the method of bringing the proceedings, the same issues are to be determined at the hearing. If the court finds that the article is adulterated or misbranded, it may enter a decree that such article be destroyed at the expense of the claimant, under the supervision of an agent of the board. All court costs and fees and storage and other proper expenses shall be taxed against the claimant or his agent.[28] On the other hand if the adulteration or misbranding can be corrected by proper labeling or processing, after the entry of the decree and after costs, fees and expenses have been paid and a good and sufficient bond has been executed, the court may make an order directing that the article be delivered to the claimant for such labeling or processing under the supervision of an agent of the board. Expense of such supervision shall be paid by the claimant.[29]

The state Pure Food and Pure Drug Laws follow to some extent in outline form the Federal Food, Drug, and Cosmetic Act, but you should not assume that the state and federal acts are identical, although many sections of the acts are word for word the same. Other than usual criminal proceedings for violations of the act, the outstanding differences in the enforcement of the statutes and the normal state statute are the provisions for a hearing before the bureau, which hearing shall be private and not open to the public. The second provides for an *in rem* proceeding which may be initiated by the board, or if thirty days have lapsed may be initiated by the claimant. **[The End]**

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[26] Footnote 1, Section 26366.
[27] Footnote 1, Section 26366.5.
[28] Footnote 1, Section 26367.
[29] Footnote 1, Section 26368.

REPORTS TO THE READER—Continued from page 246

bacitracin ointment. All amendments are currently in effect.

FSA Announcements. — Federal Security Administrator Oscar R. Ewing states that no action will be recommended against pasteurized process cheese food or spread solely because they include skim milk cheese for manufacturing. A hearing will be called as soon as practicable to take evidence on proposed amendments to present definitions and standards of identity. Meanwhile, the large segment of the interested industry now urging the amendments will continue to comply with other requirements of existing regulations and provisions until the hearing is held and an order issued (16 F. R. 2722).

Also announced by the FSA was the fact that extracts made from the suprarenal glands of hogs which have not been finally inspected by federal inspectors may be released for the manufacture of drugs if they have first been subjected to this treatment: Subjected to quick freezing promptly upon removal from the carcasses and maintained in a frozen state until they are ground and immersed in ninety-five per cent to 100 per cent acetone; kept in the acetone for a period of not less than six days when the mixture may be filtered and the residue must be burned (16 F. R. 2722).

In the Federal Trade Commission

No Beauty Aid.—Manufacturers of Nadinola Bleaching Cream and Nadinola Freckle Cream have been ordered in FTC Docket No. 5342 to cease advertising that their cosmetic preparations are competent treatments for pimples or skin blemishes. The Tennessee company is prohibited from representing that its preparations have any beneficial effect on blemishes except to the extent that they may temporarily protect the skin, thus facilitating the normal processes of the skin in clearing up minor externally caused blemishes. One allegation of the complaint was not sustained by the evidence; it charged that the corporation represented its preparations as capable of removing blackheads, whereas the record showed that it only claimed that the preparation would lessen blackheads.

FTC Appeals Injunction Denial.—Denial of a preliminary injunction by the United States District Court for the Northern District of Illinois in the *Imdrin* case has prompted the FTC to instruct its general counsel to appeal. The suit asked for the preliminary injunction pending final disposition of a Commission proceeding charging misrepresentation of the therapeutic properties and effectiveness of the medicinal preparation in the treatment of arthritis, rheumatism, sciatica and other diseases.

In its suit, the Commission said that the defendants have "persisted" in disseminating on a national scale false advertisements of their product since the issuance of a complaint in August of 1949, and that a court injunction is the only means of stopping the misrepresentation pending issuance of a cease and desist order. The Illinois court in denying the injunction ruled that the Commission had "failed to maintain its burden," and that there

were no "special circumstances . . . to warrant issuance of the injunction in order to prevent irreparable injury" (Federal Trade Commission Release).

In the Department of Agriculture

Lilies for Arthritics.—In the intensive search for plant sources for the new antiarthritic drug, cortisone, it has been discovered that the lily family contains to a large degree the steroids which can be synthesized into the drug. This progress in the research of USDA and the Public Health Service was revealed at the recent meeting of the Experiment Station Directors of Northeastern States in Philadelphia. Cortisone is now made from ox bile, an inadequate and expensive source. With the discovery made that many plants contain steroids, the problem now is to find a plant containing enough of them to justify development of species into a crop plant. The plant hunters are concentrating on the lily family and those closely related to it as the best-known source.

Discovery in Fruit Precooling.—Department engineers working at Wenatchee, Washington, have found that they can cool fruit in a high-velocity, cold-air tunnel many times more rapidly than it is normally cooled if placed directly into cold storage. This rapid cooling may lead to improved handling and storage for this important Pacific Northwest industry as it would lengthen considerably the time that fruit can be held safely in cold storage and help prevent the growth of rot-producing diseases.

Canned Fruits and Vegetables for Servicemen.—Government measures to meet the problem of providing the armed services with essential supplies of canned fruits and vegetables were under discussion at the USDA's Fruit and Vegetable Advisory Committee's first meeting, March 22-26. Special problems of government and industry arising from the defense mobilization program—manpower problems in the canning industry, the tin outlook, plant equipment and transportation and material problems—were the major subjects concerning the committee.

Increased Emphasis on Disseminating Research Results.—Greater stress on all methods of making known results of research was recommended by the Agricultural Research Policy Committee as an aid in national mobilization. This recommendation was decided on at the recent two-day meeting of USDA officials and committee members. At the invitation of Secretary Brannan, the committee will meet with the CCC Advisory Board April 26 and 27 in Washington. The two groups constitute the Agricultural Mobilization Policy Board recently named by the Secretary.

Surveys Europe's Fat and Oil Situation.—A brief study of the fats and oils marketing situation in several Western European countries is underway. The Department is conducting the study under the provisions of the Research and Marketing Act. Observations are being made by Paul E. Quintus, head of the Fats and Oils Division, Office of Foreign Agricultural Relations. Mr. Quintus has been in Europe since January 1 as a delegate to the third round of tariff negotiations under the General Agreement on Tariffs and Trade at Torquary, England. His investigation is taking him into Belgium, Western Germany, France, England and possibly the Netherlands.

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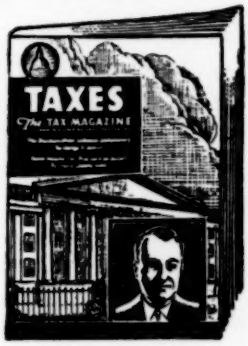

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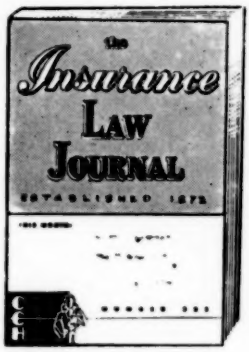

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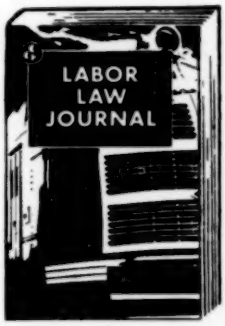

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